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Golan

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(54) **FRACTURING CALCIFICATIONS IN HEART VALVES**

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(73) Assignee: **Pi-Cardia Ltd.**, Rehovot (IL)

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§ 371 (c)(1),
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PCT Pub. Date: **Jun. 9, 2011**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61B 17/22 (2006.01)
A61B 17/221 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/22031*** (2013.01); ***A61B 17/22*** (2013.01); ***A61B 17/221*** (2013.01); *A61B 2017/22098* (2013.01); *A61B 2090/064* (2016.02)

(58) **Field of Classification Search**
CPC A61F 2/01; A61F 2002/011; A61B 17/221; A61B 17/320758; A61B 17/12172; A61B 17/12109;A61B 17/320725; A61B 17/3207; A61B 2017/22034; A61B 2017/22098; A61B 17/22; A61B 2017/22091
USPC ... 606/127, 128, 159, 167, 170; 604/22, 508
See application file for complete search history.

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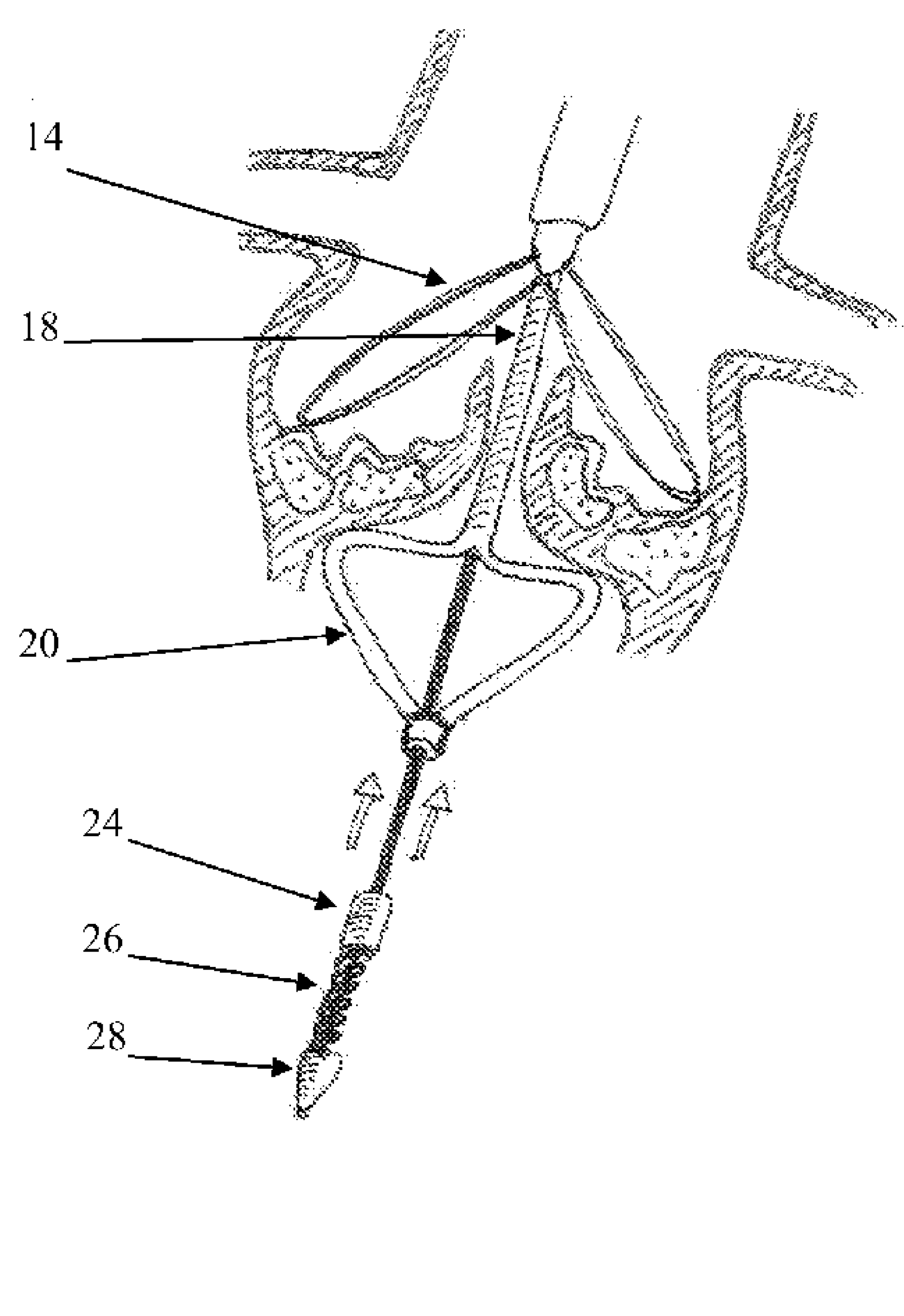
(74) *Attorney, Agent, or Firm* — Dekel Patent Ltd.; David Klein

(57) **ABSTRACT**

A device for fracturing calcifications in heart valves including an expandable stabilizer (**14**) and expandable impactor arms (**20**) assembled on and deployed by a delivery system (**10**), wherein the delivery system (**10**) is operable to move the impactor arms (**20**), while in an expanded position, with respect to the stabilizer (**14**) with sufficient energy so as to fracture a calcification located in tissure which is sandwiched between the stabilizer (**14**) and the impactor arms (**20**).

15 Claims, 21 Drawing Sheets



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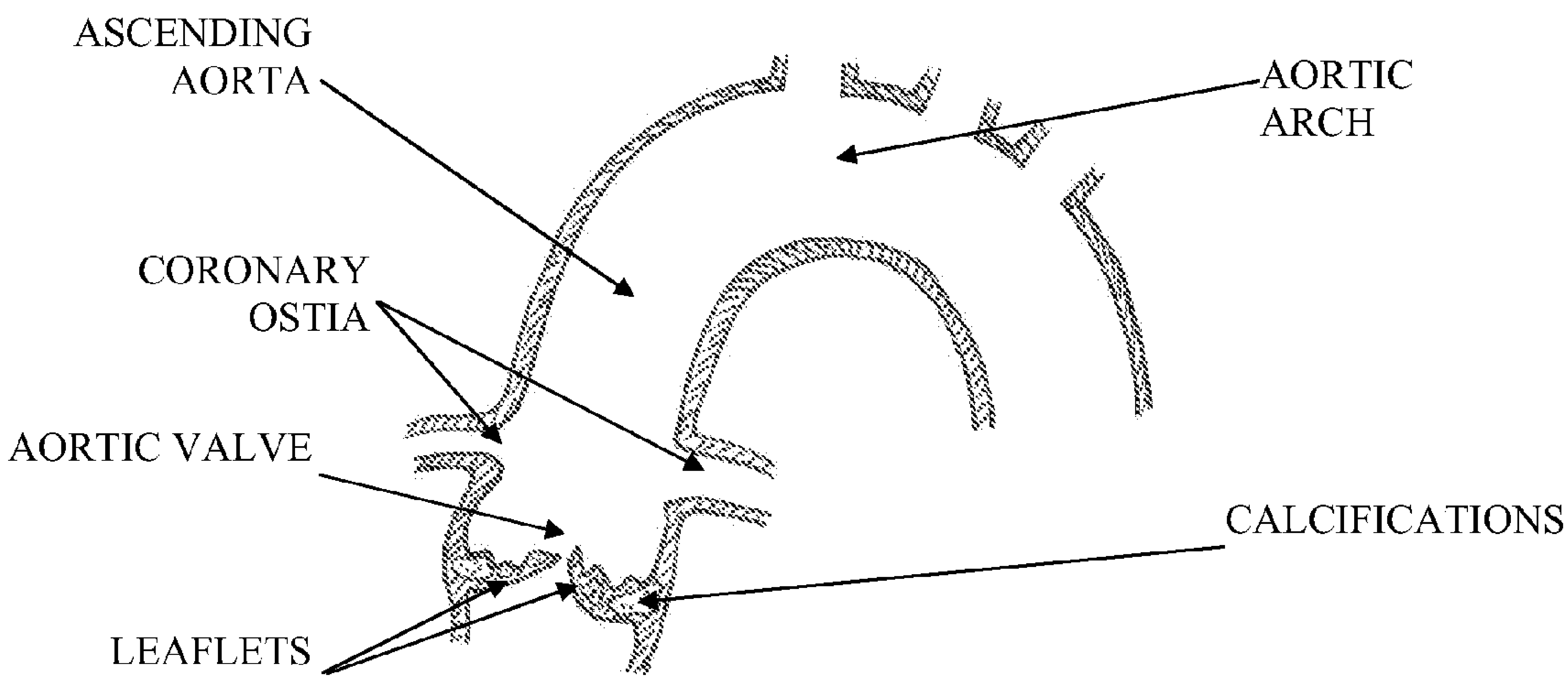

ASCENDING AORTA
AORTIC ARCH
CORONARY OSTIA
AORTIC VALVE
CALCIFICATIONS
LEAFLETS

FIG. 1

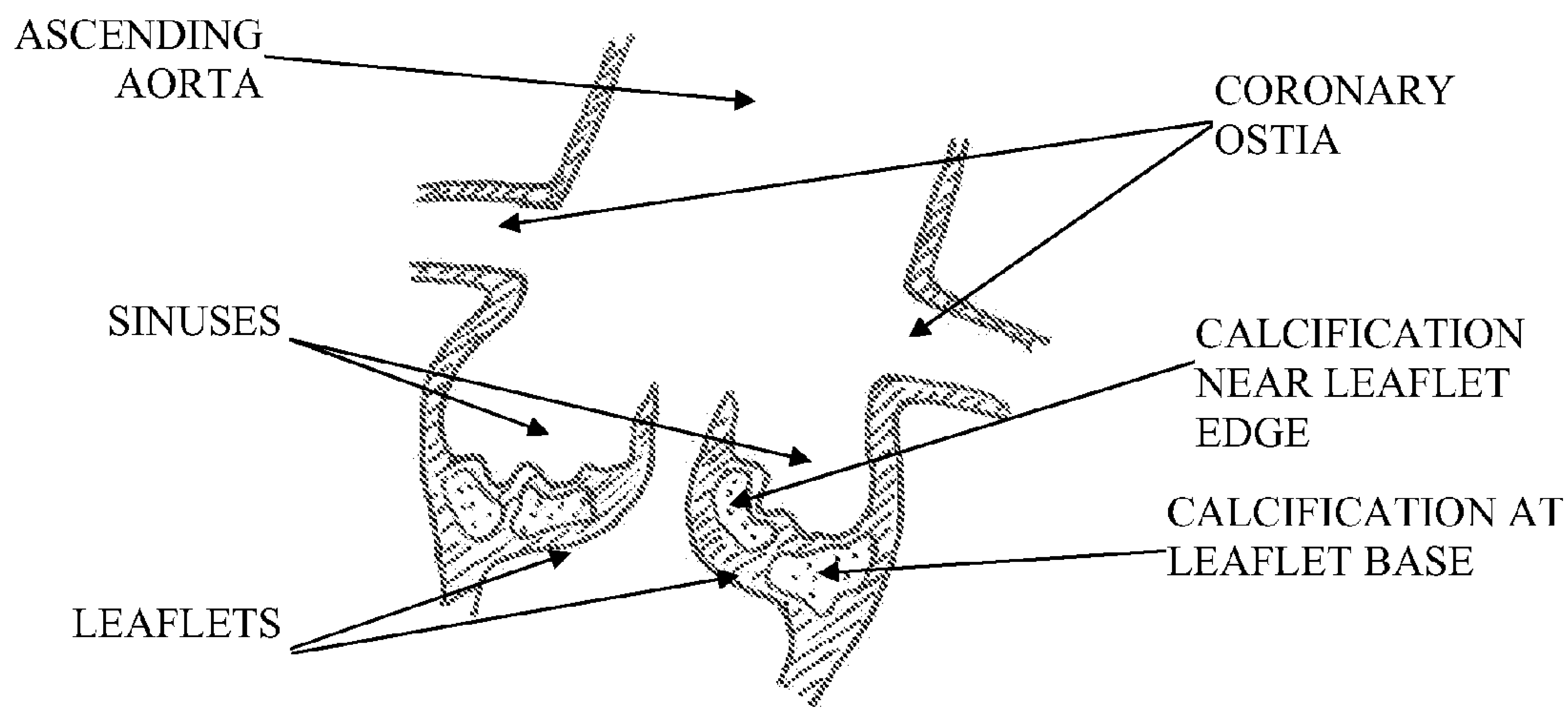

ASCENDING AORTA
CORONARY OSTIA
SINUSES
CALCIFICATION NEAR LEAFLET EDGE
CALCIFICATION AT LEAFLET BASE
LEAFLETS

FIG. 2

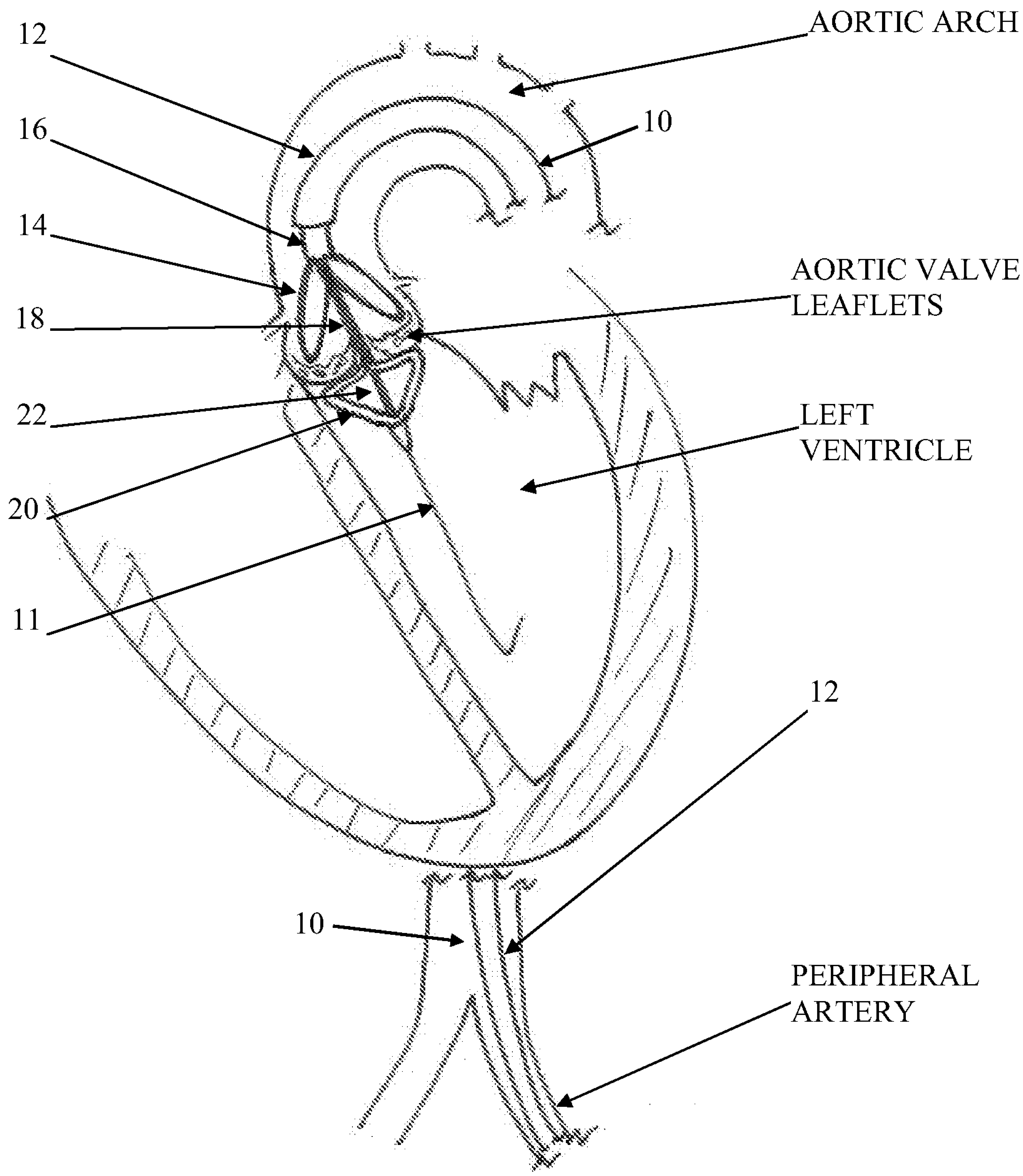

12
AORTIC ARCH
16
10
14
AORTIC VALVE
LEAFLETS
18
22
LEFT
VENTRICLE
20
11
12
10
PERIPHERAL
ARTERY

FIG. 3

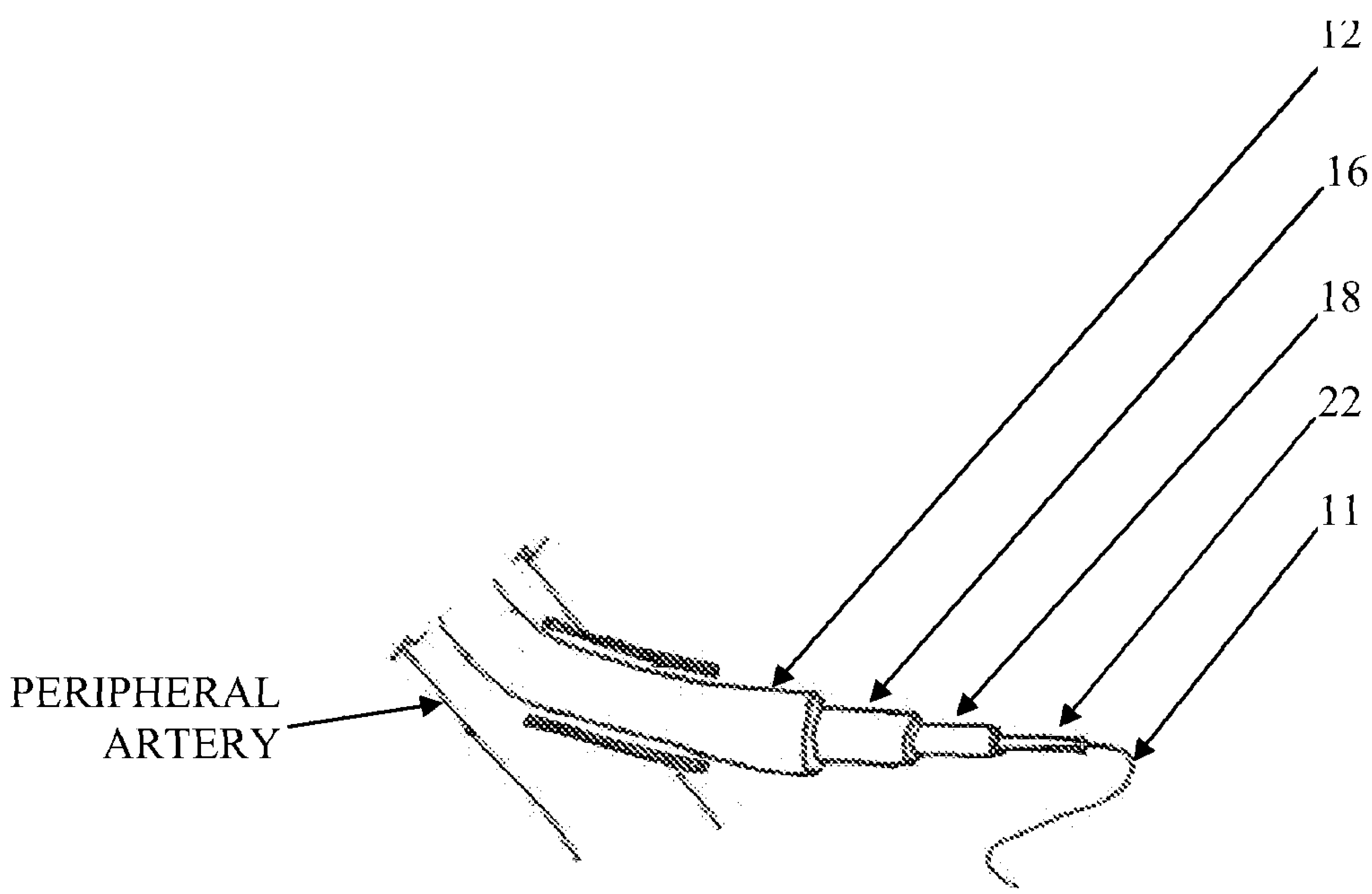


FIG. 4

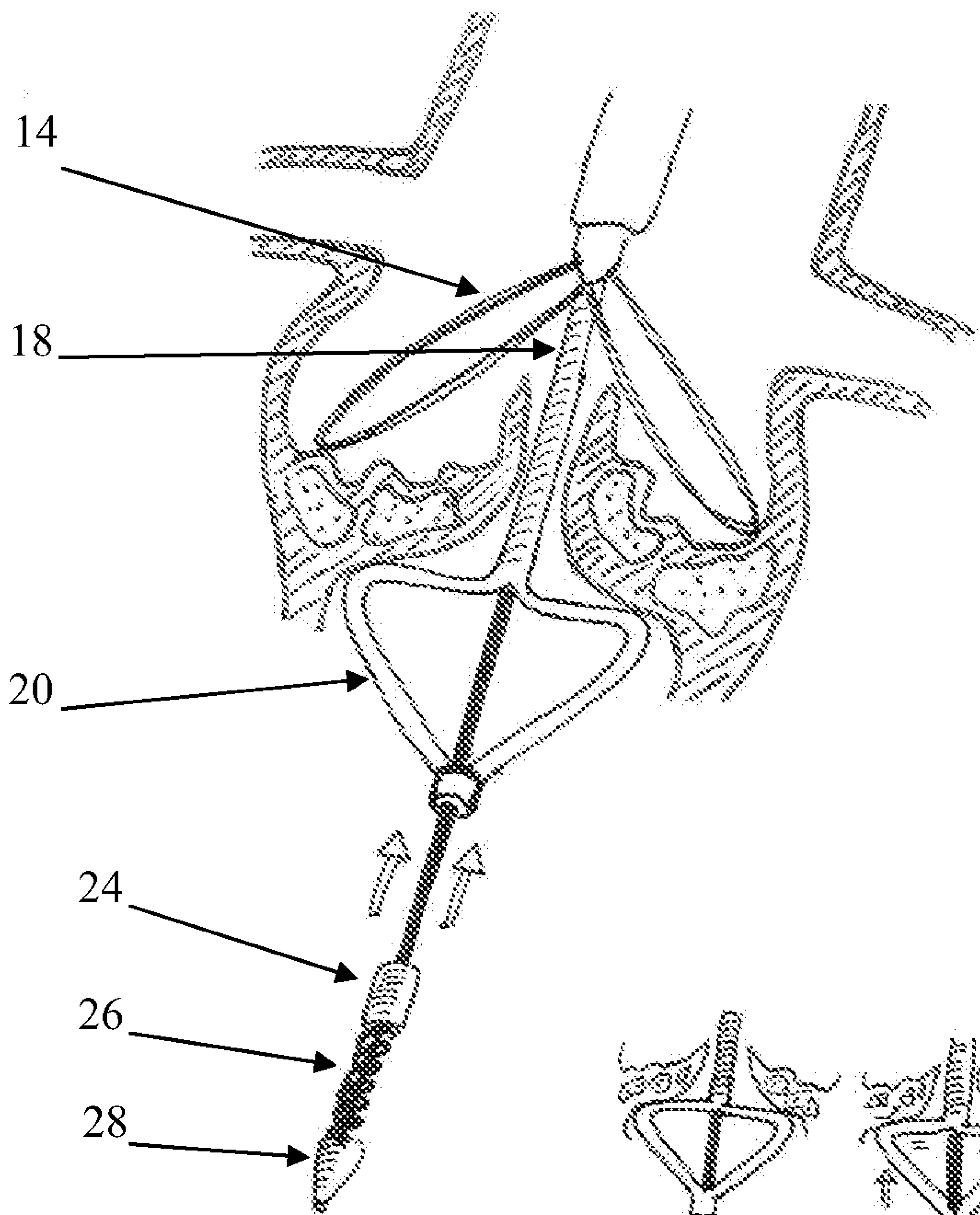


FIG. 5

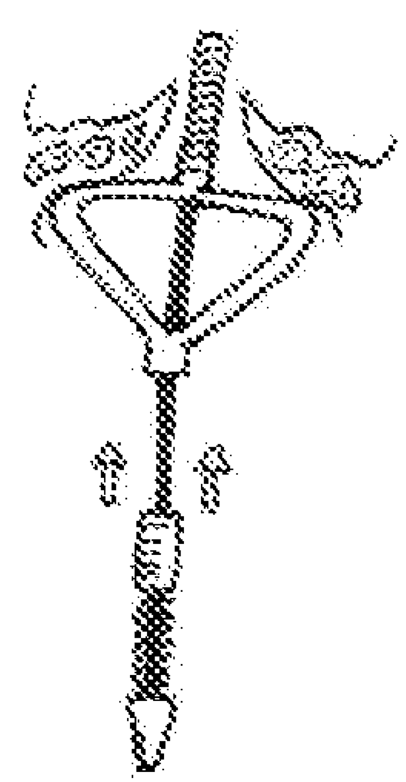


FIG. 5A

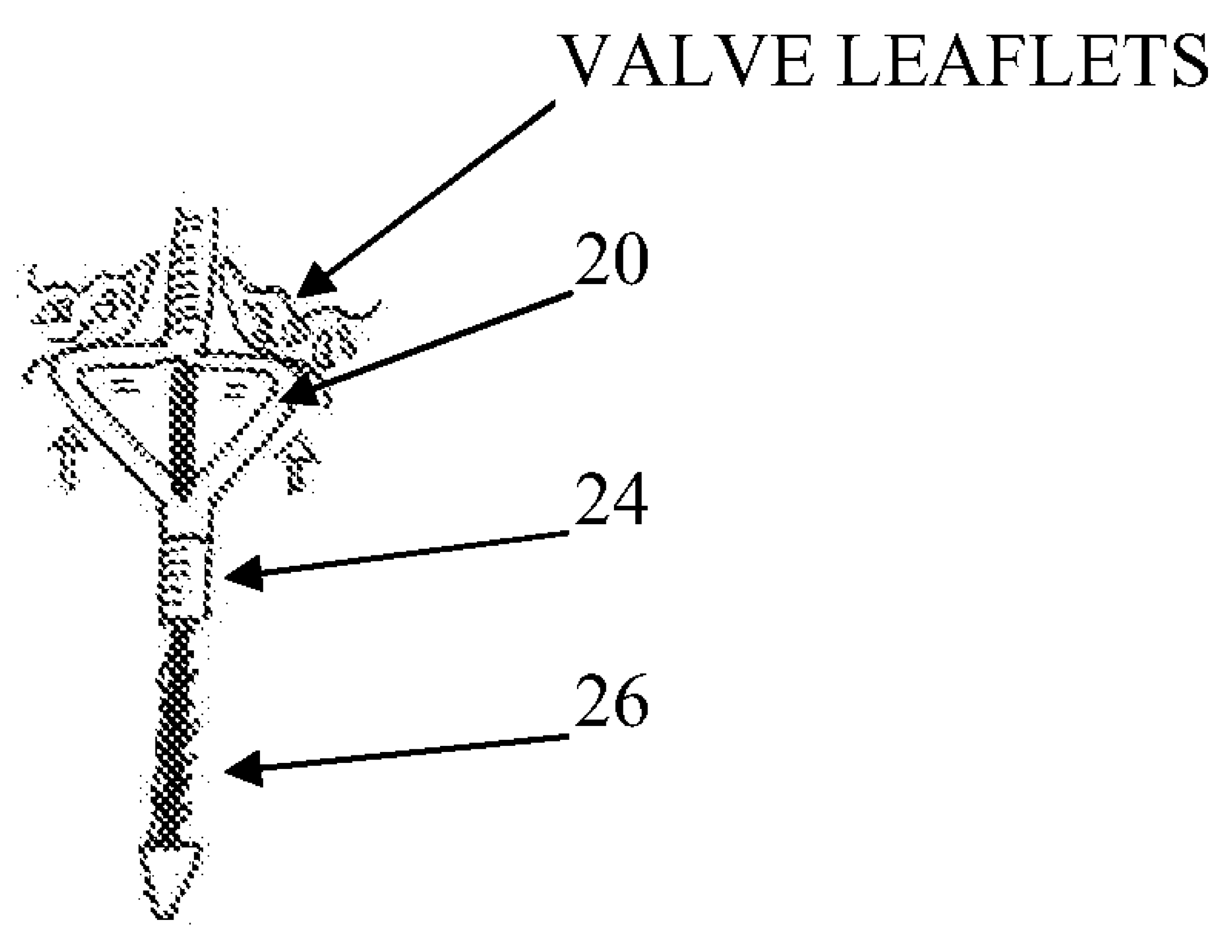


FIG. 5B

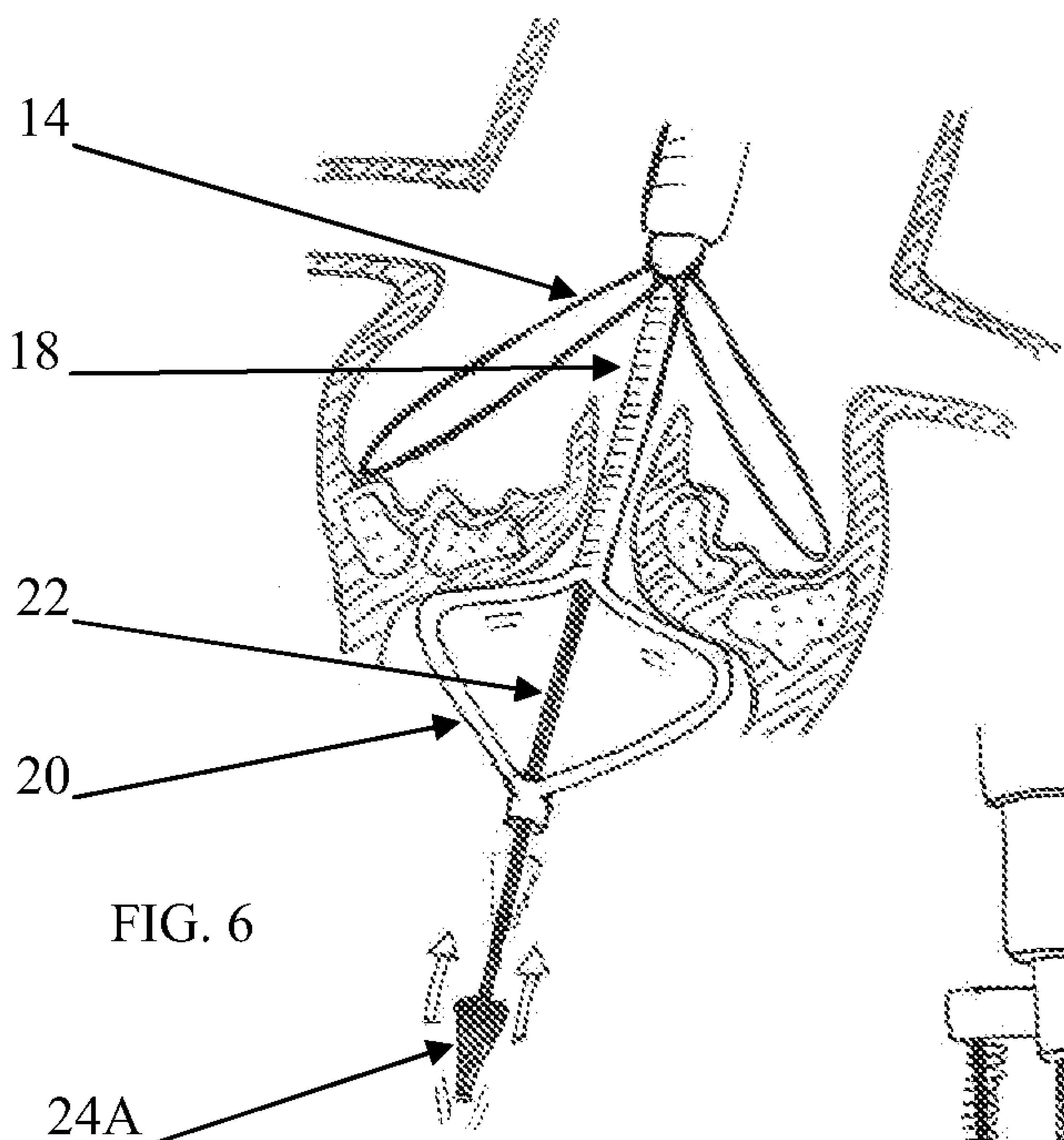


FIG. 6

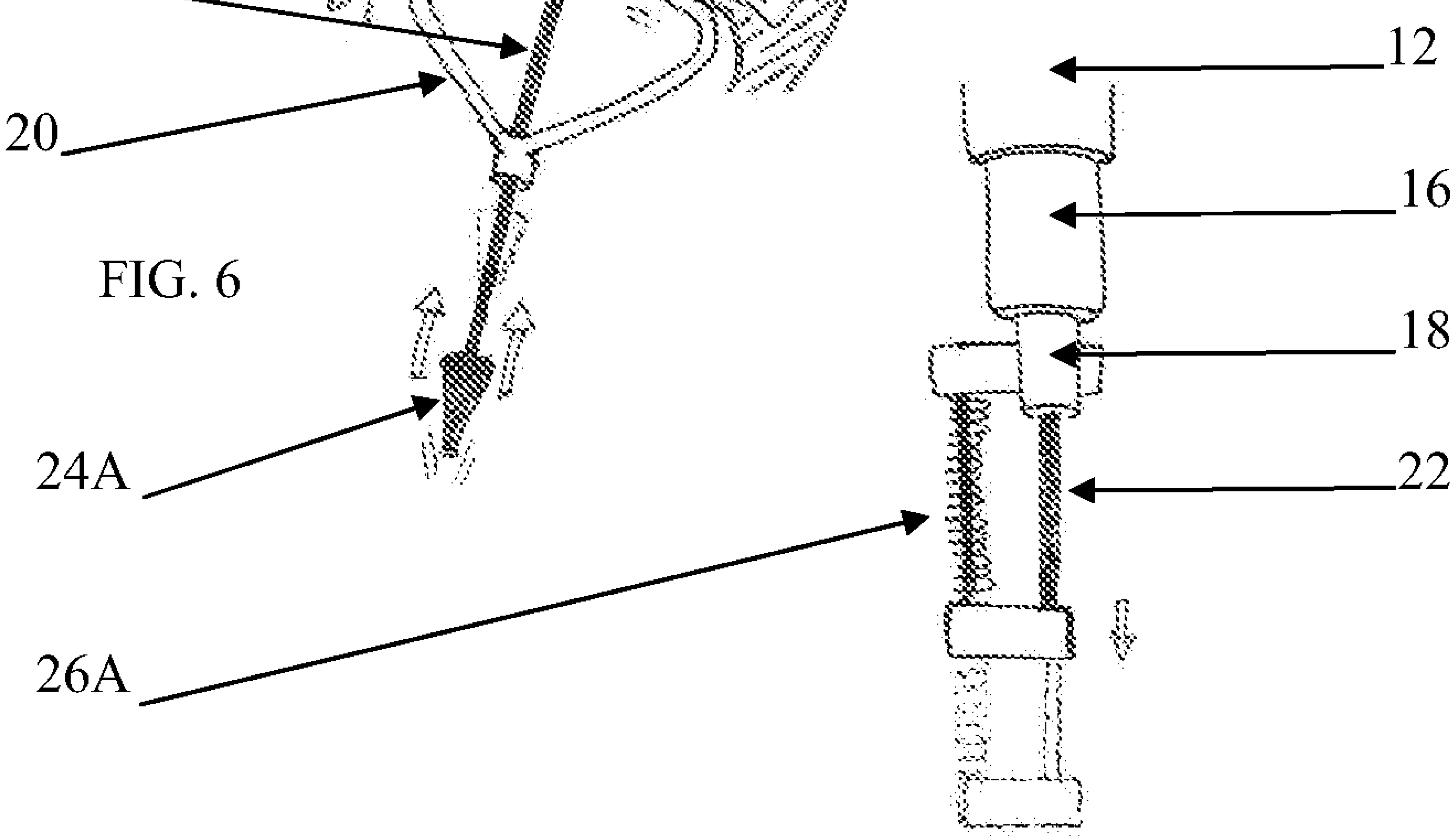


FIG. 6A

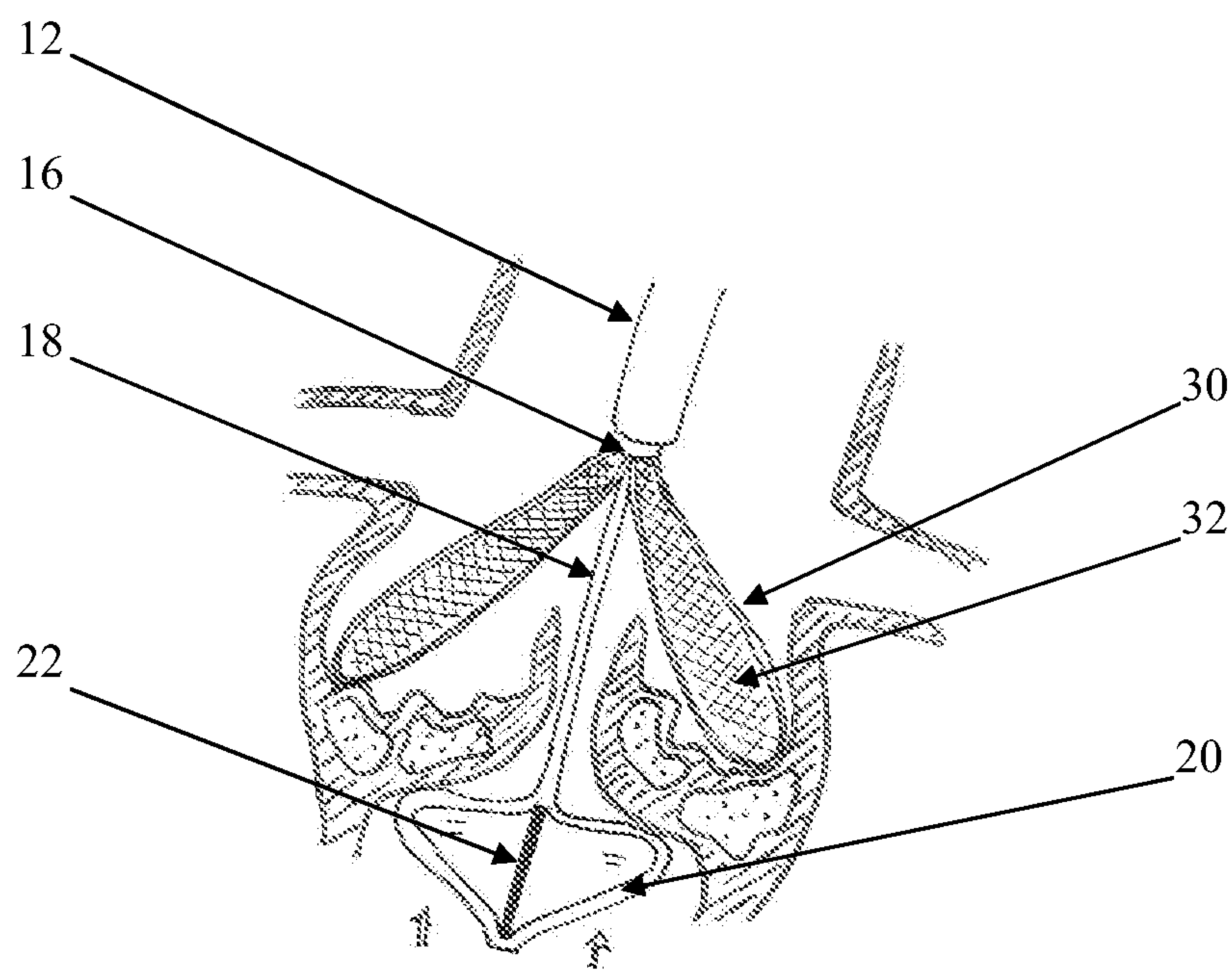


FIG. 7

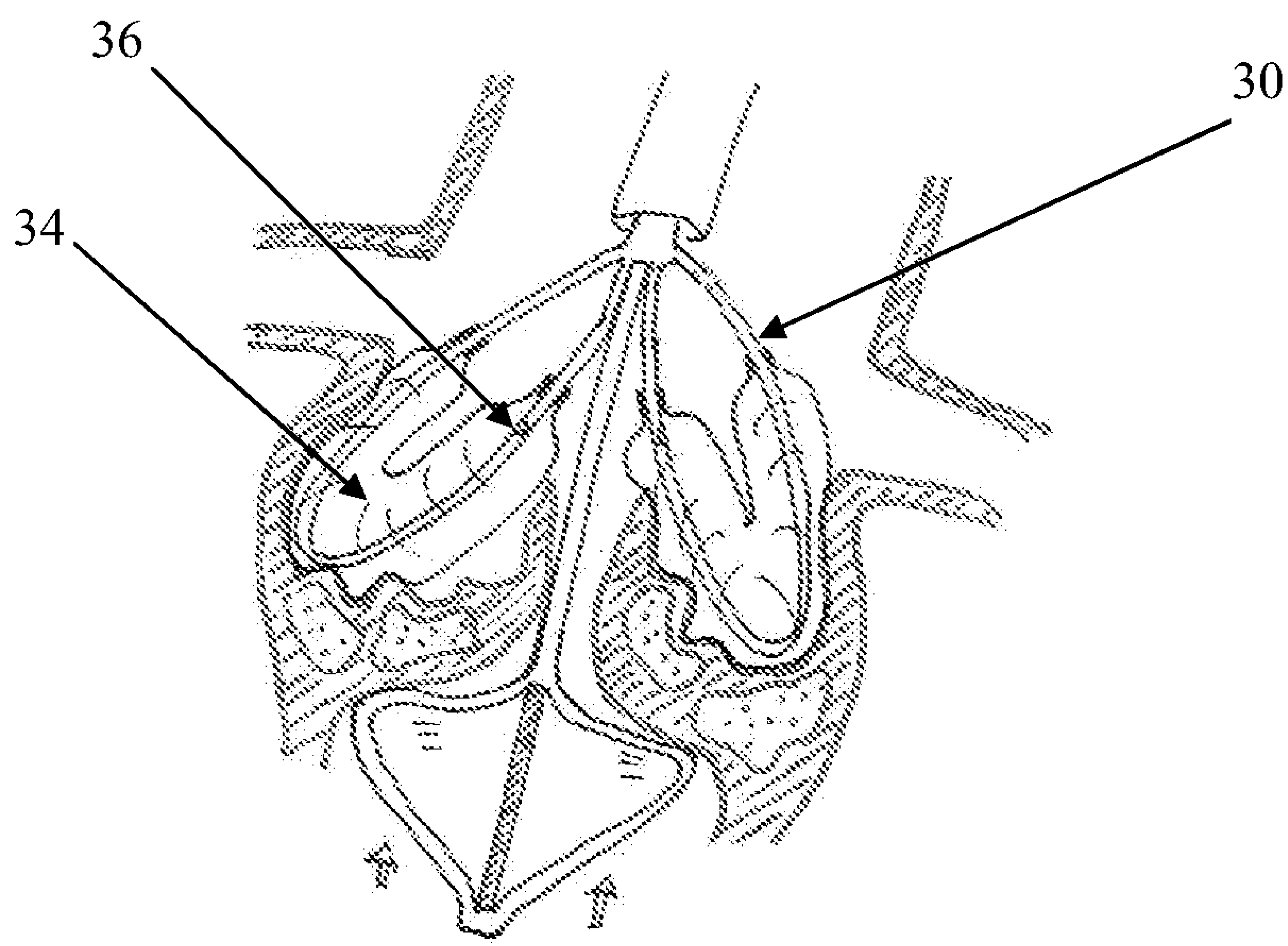


FIG. 8

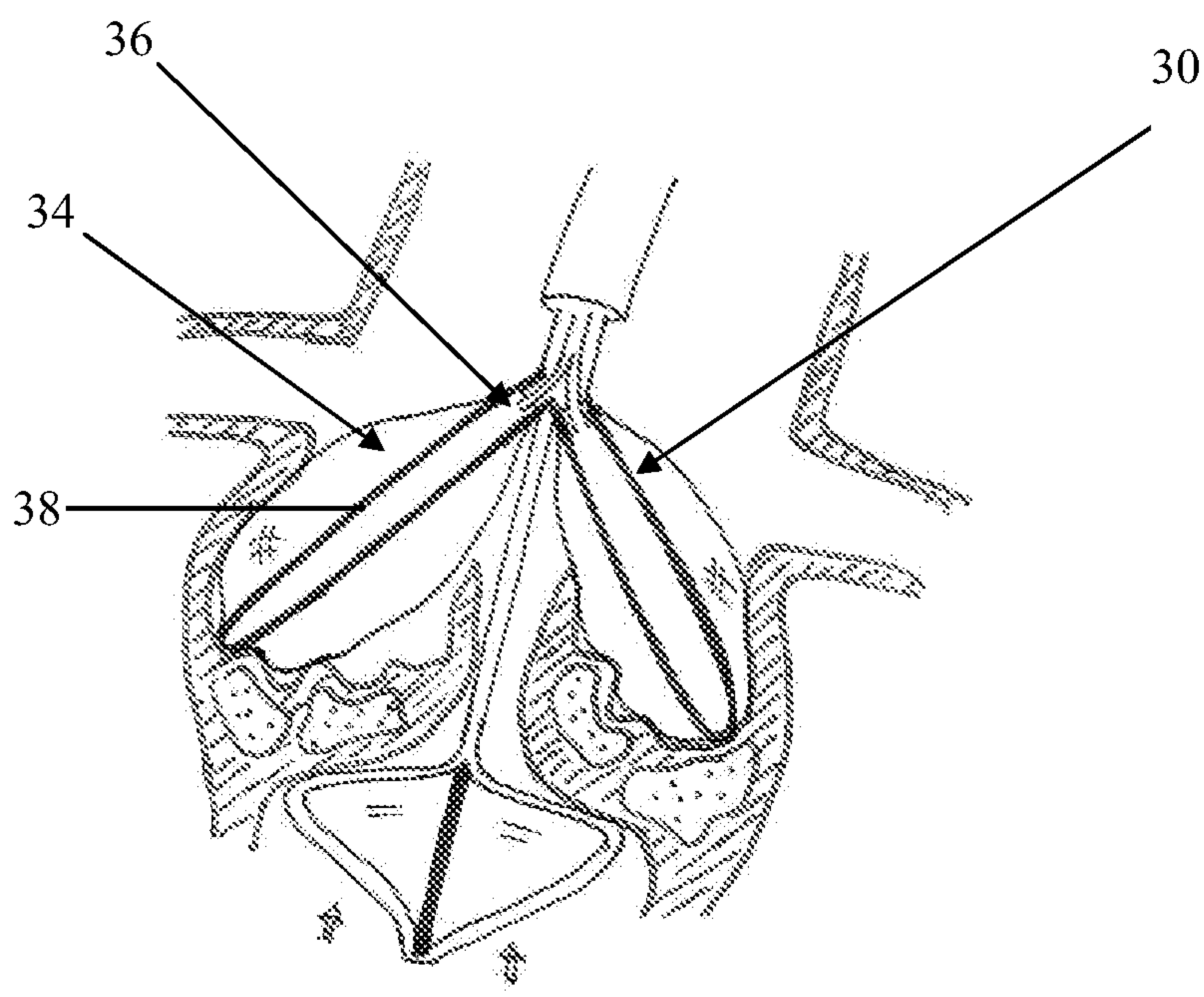


FIG. 9

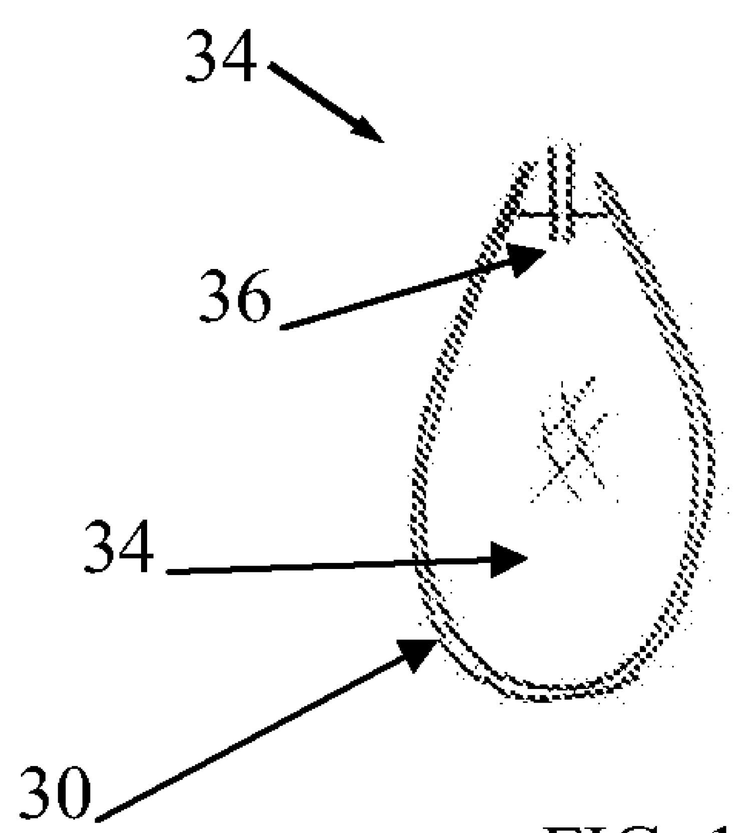


FIG. 10A

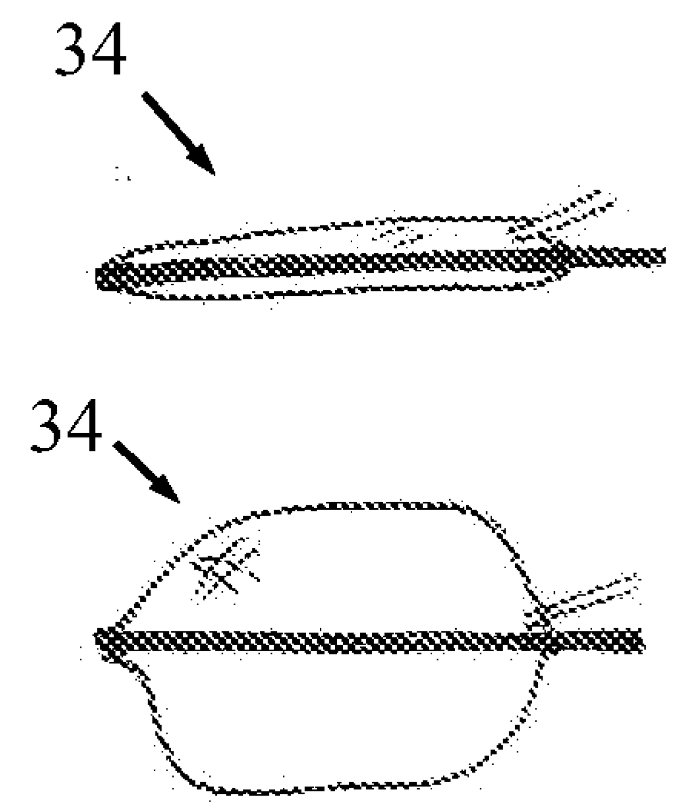


FIG. 10B

FIG. 10C

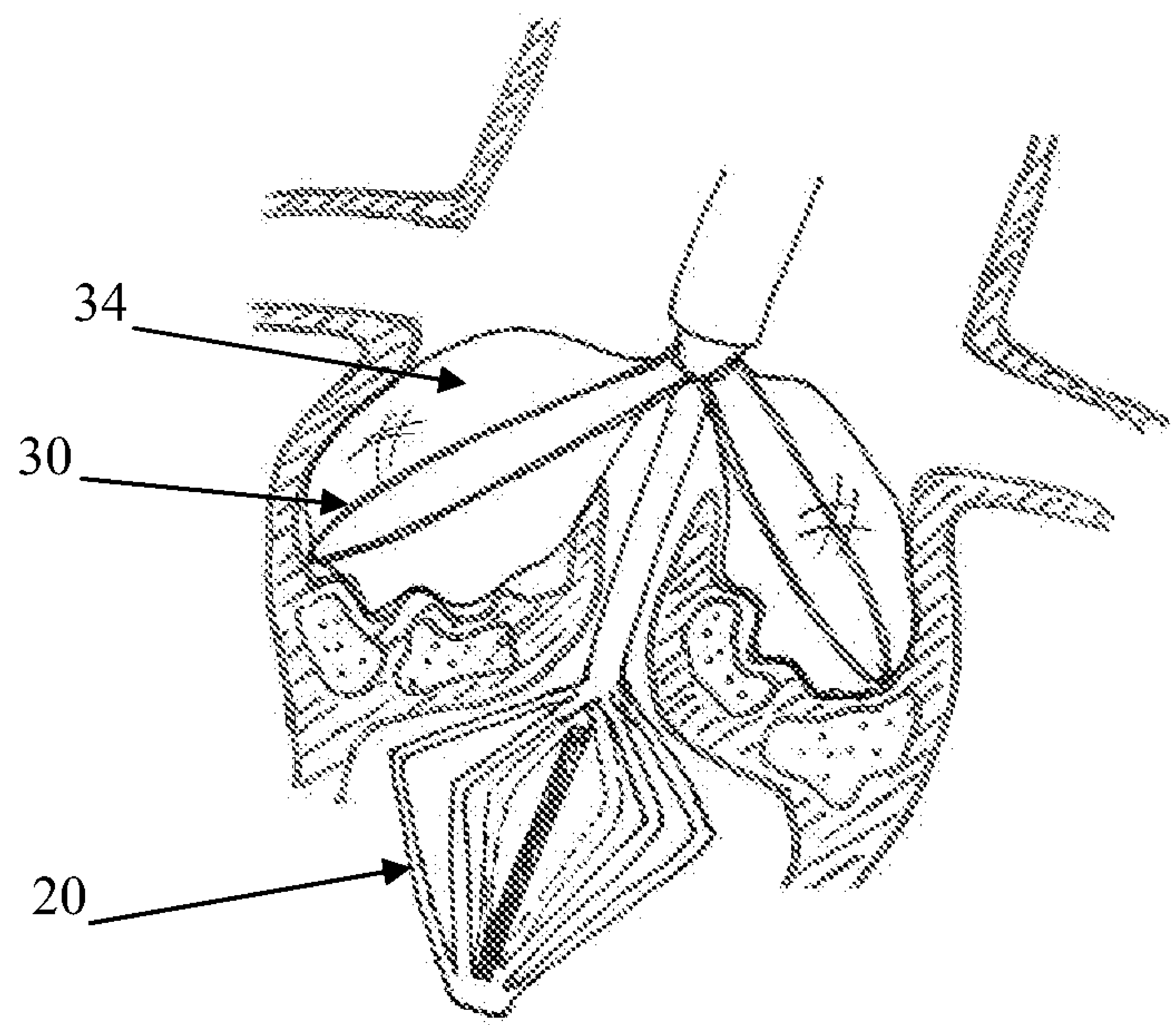


FIG. 11

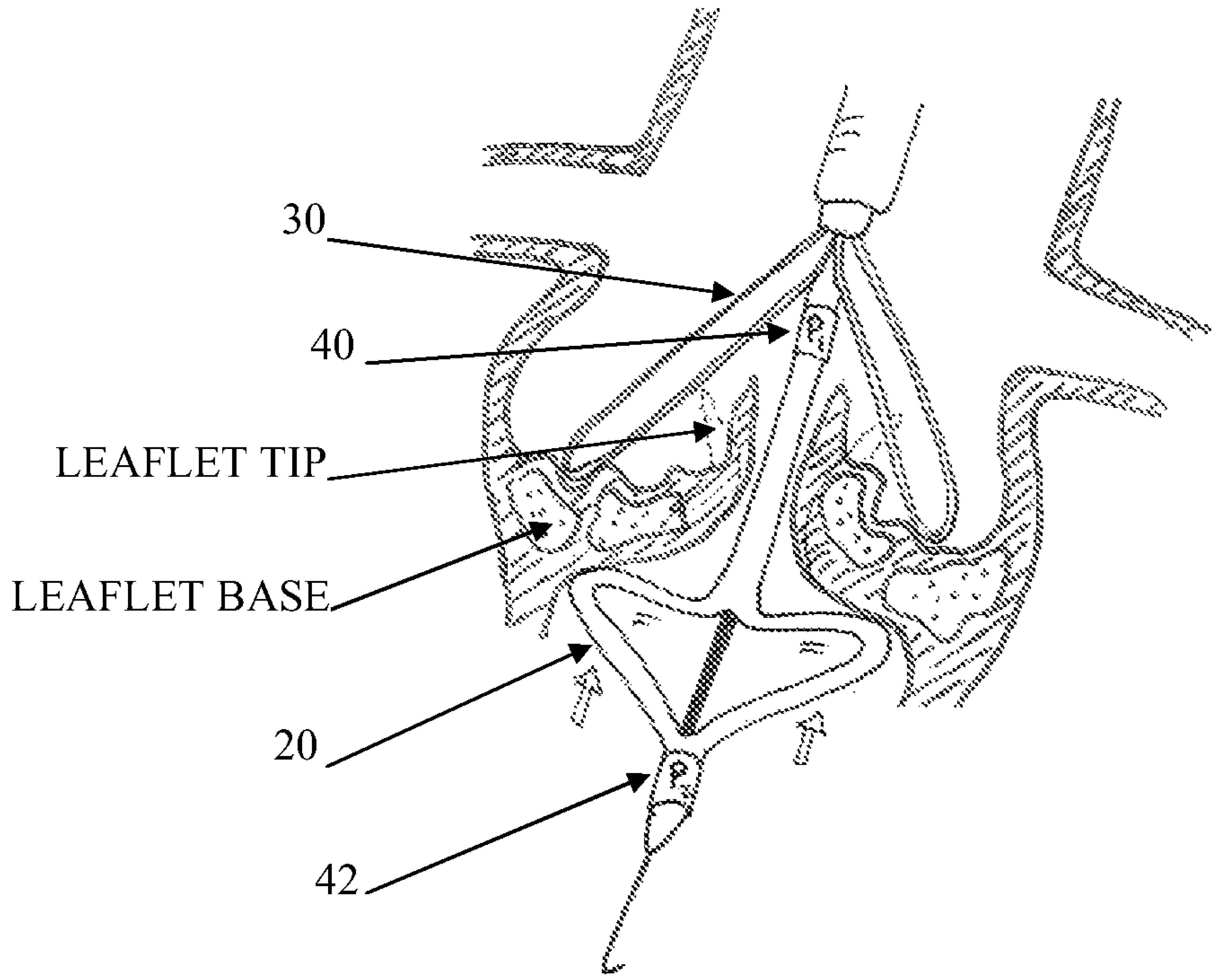


FIG. 12

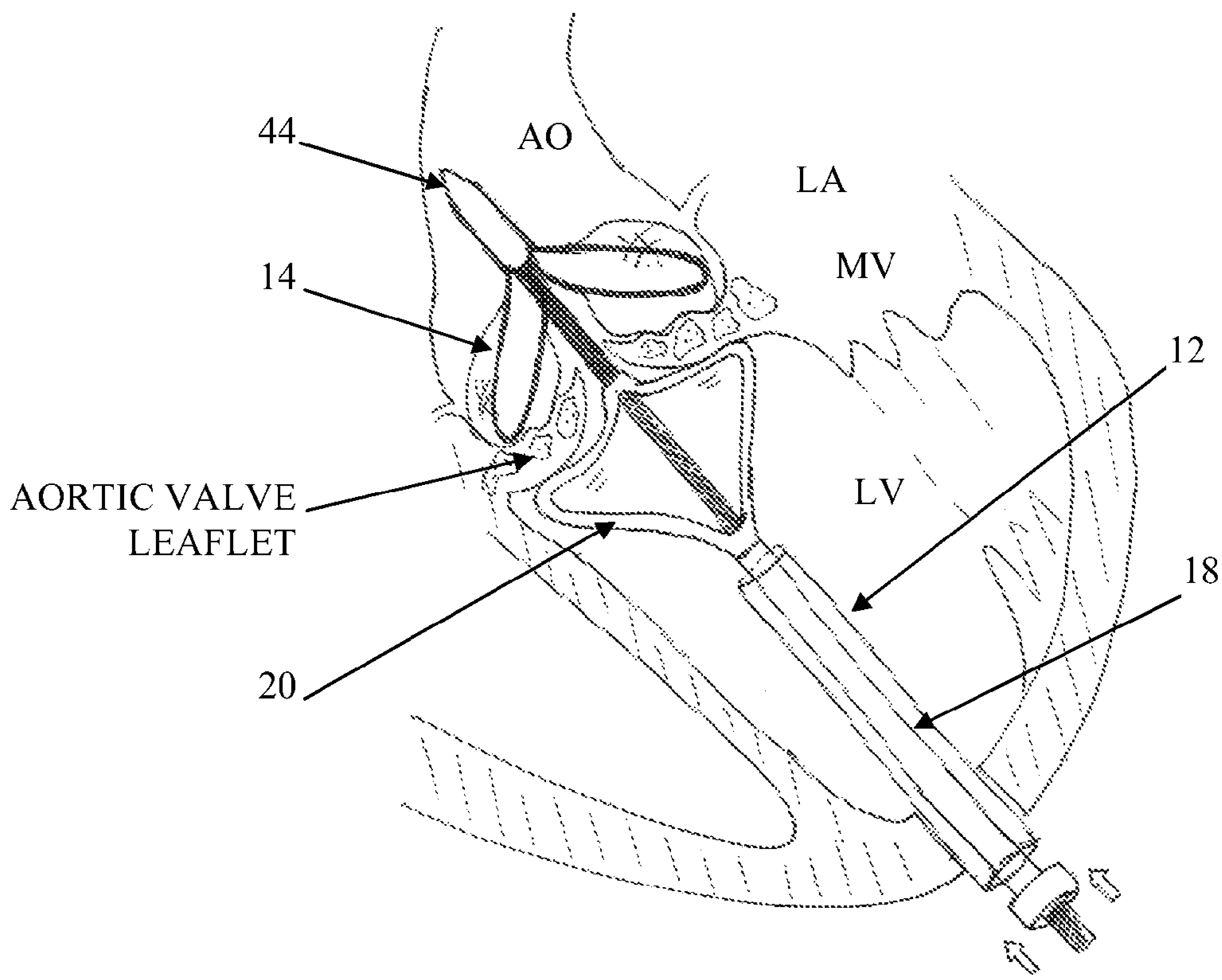


FIG. 13

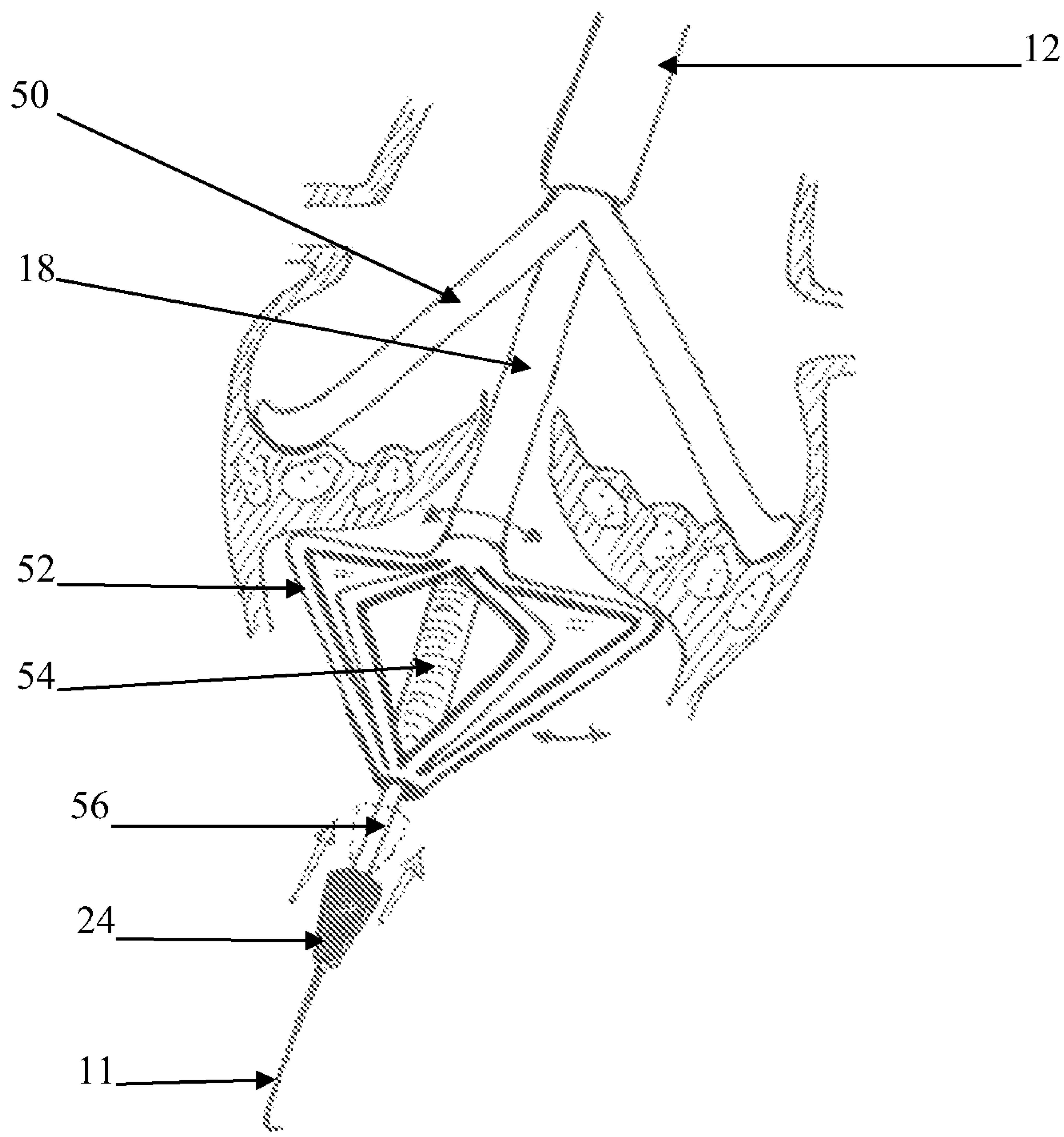


FIG. 14

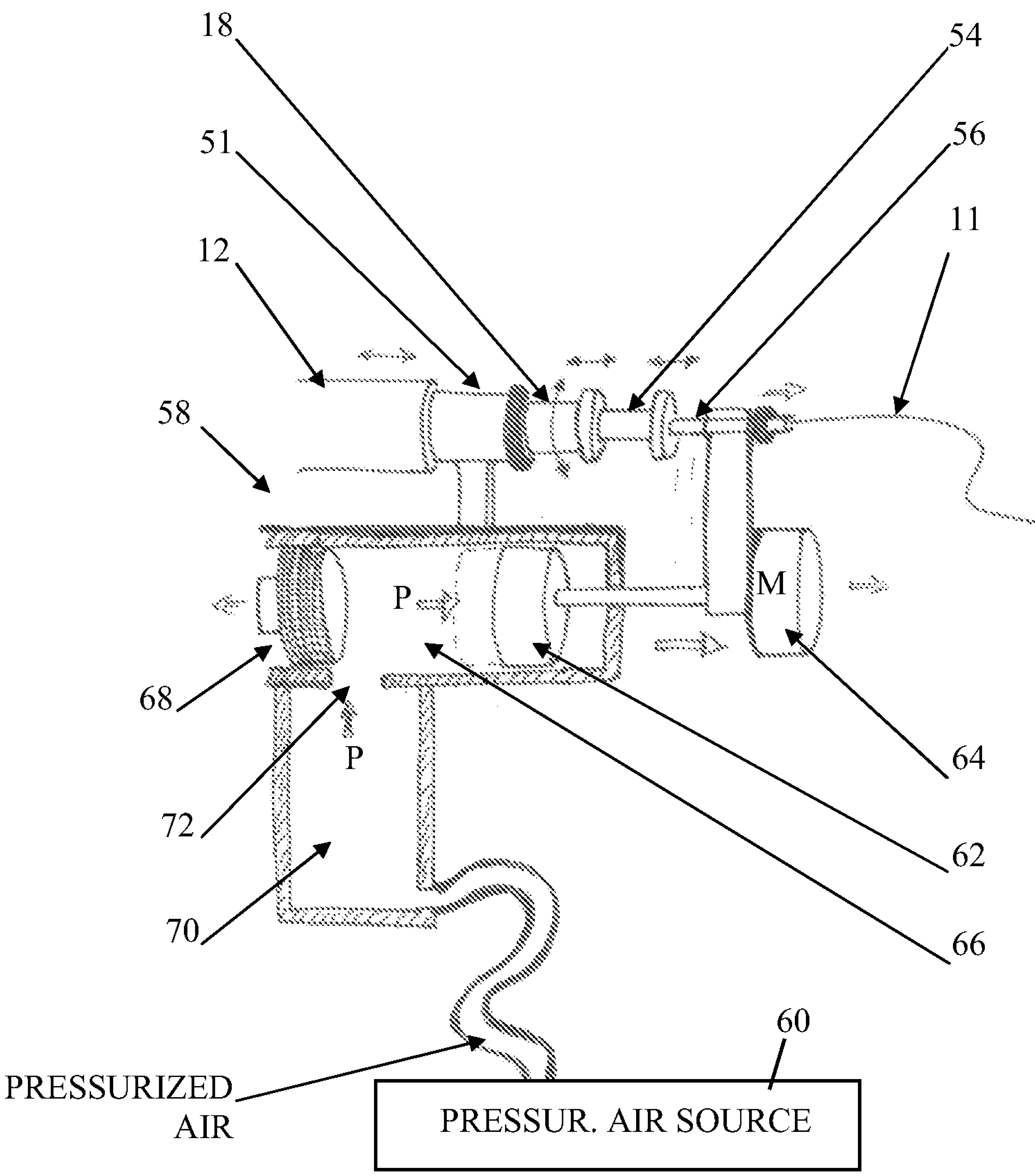

18
54
51
56
12
11
58
M
P
68
P
64
72
62
70
66
60
PRESSURIZED AIR
PRESSUR. AIR SOURCE

FIG. 15

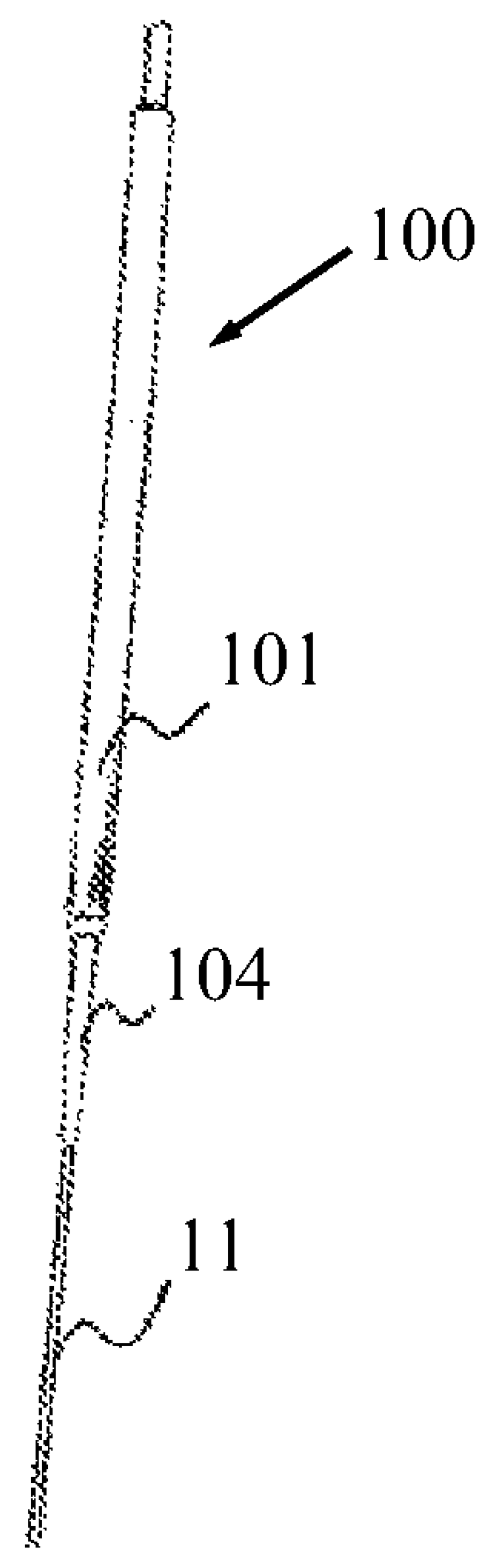


FIG. 16A

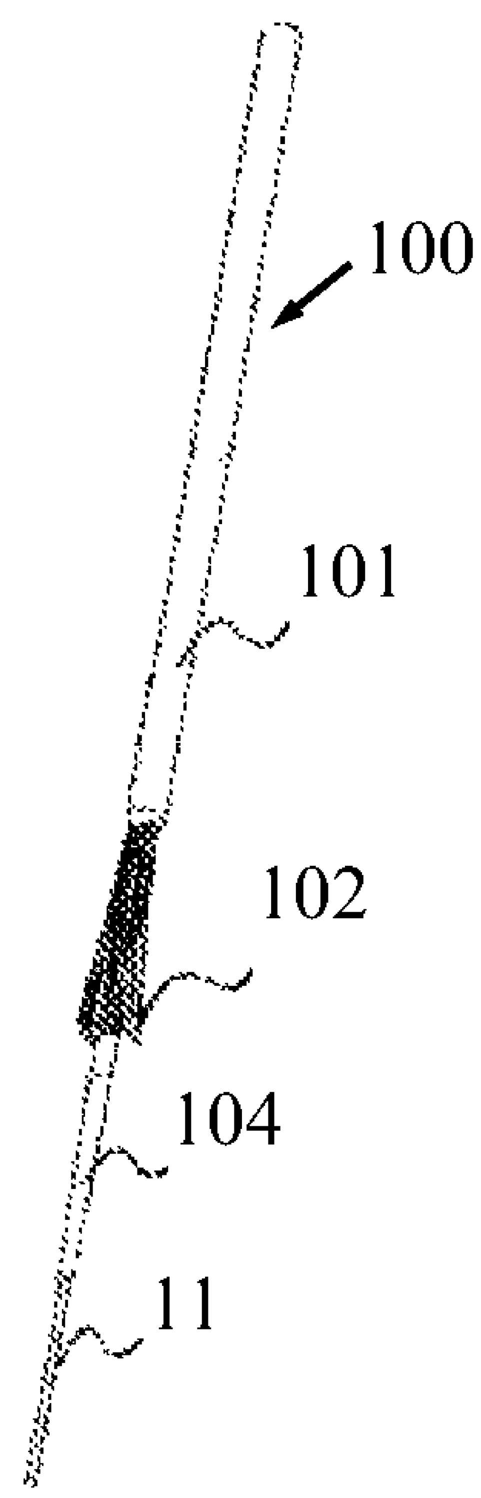


FIG. 16B

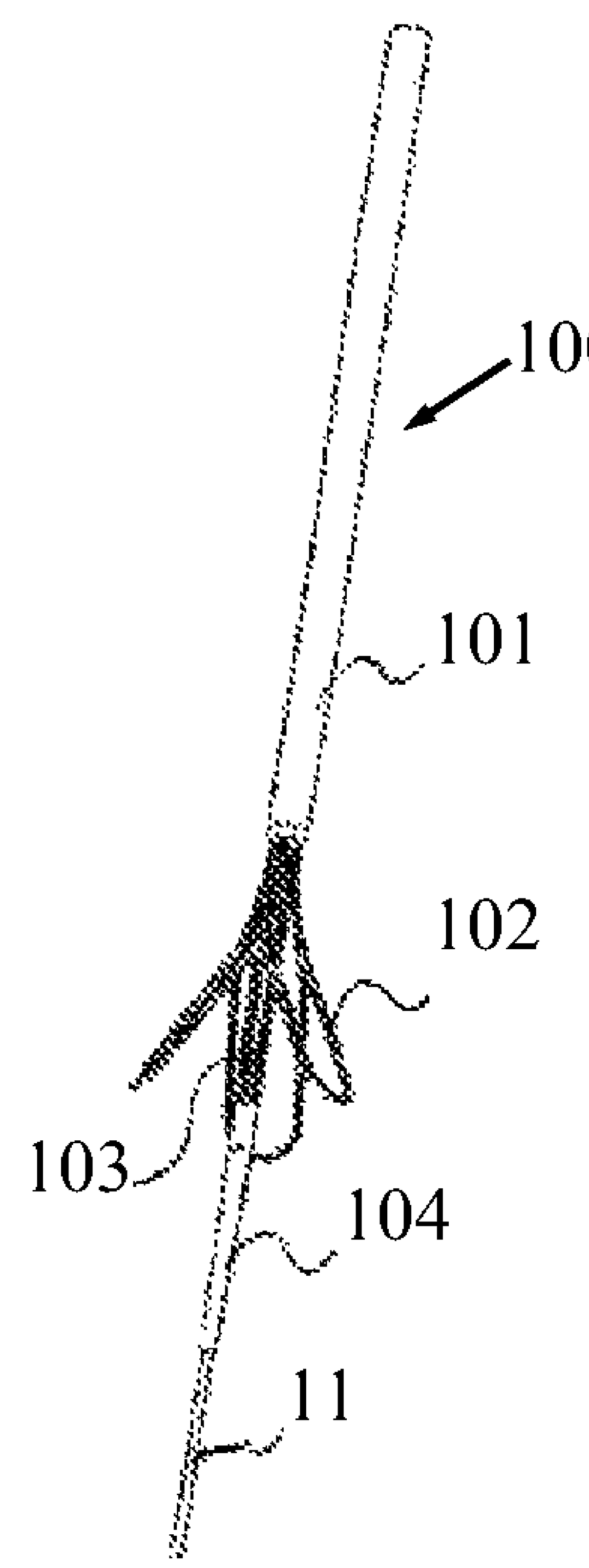


FIG. 16C

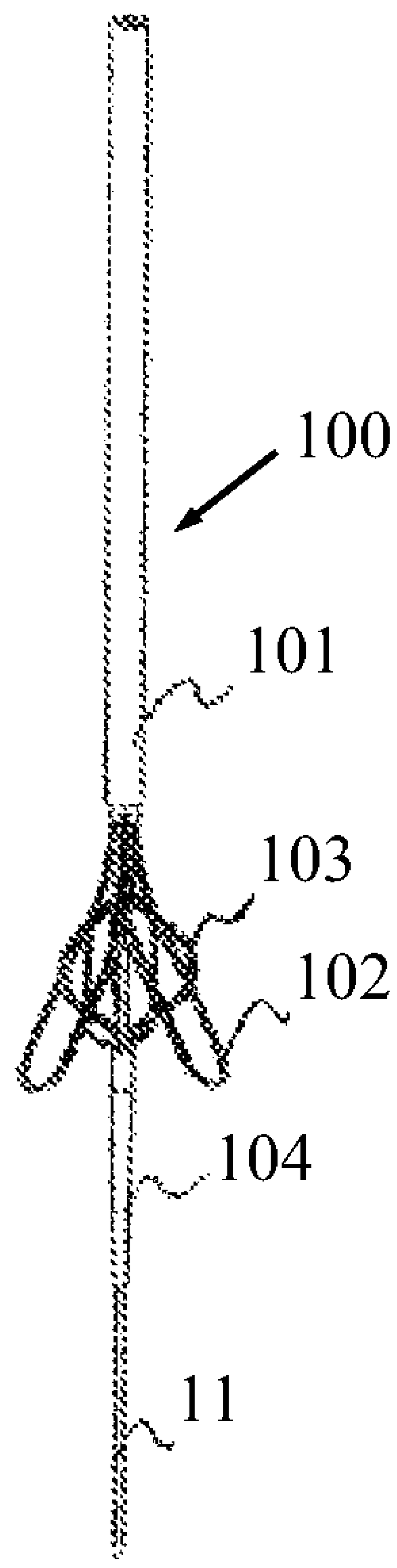


FIG. 16D

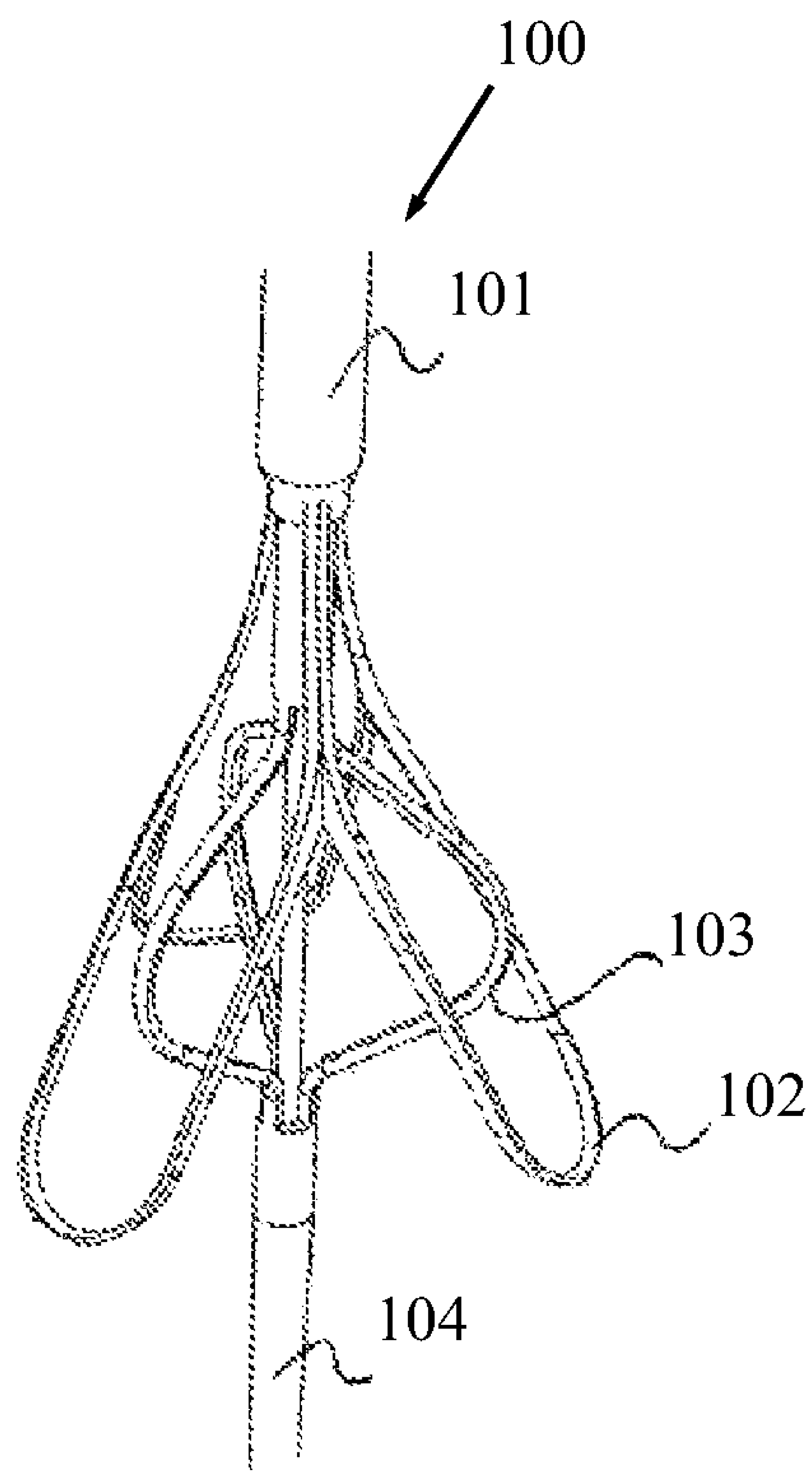


FIG. 17

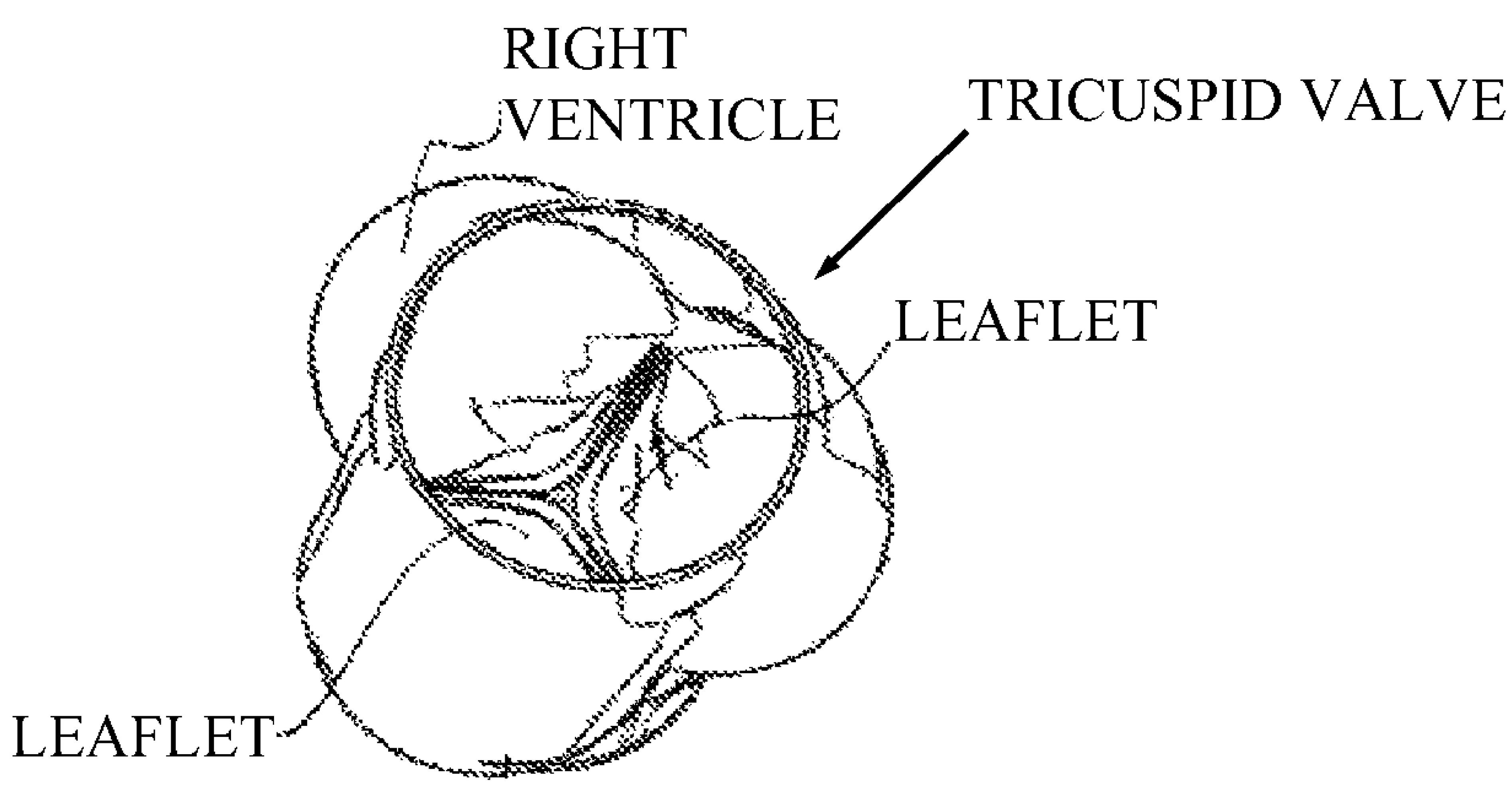


FIG. 18A

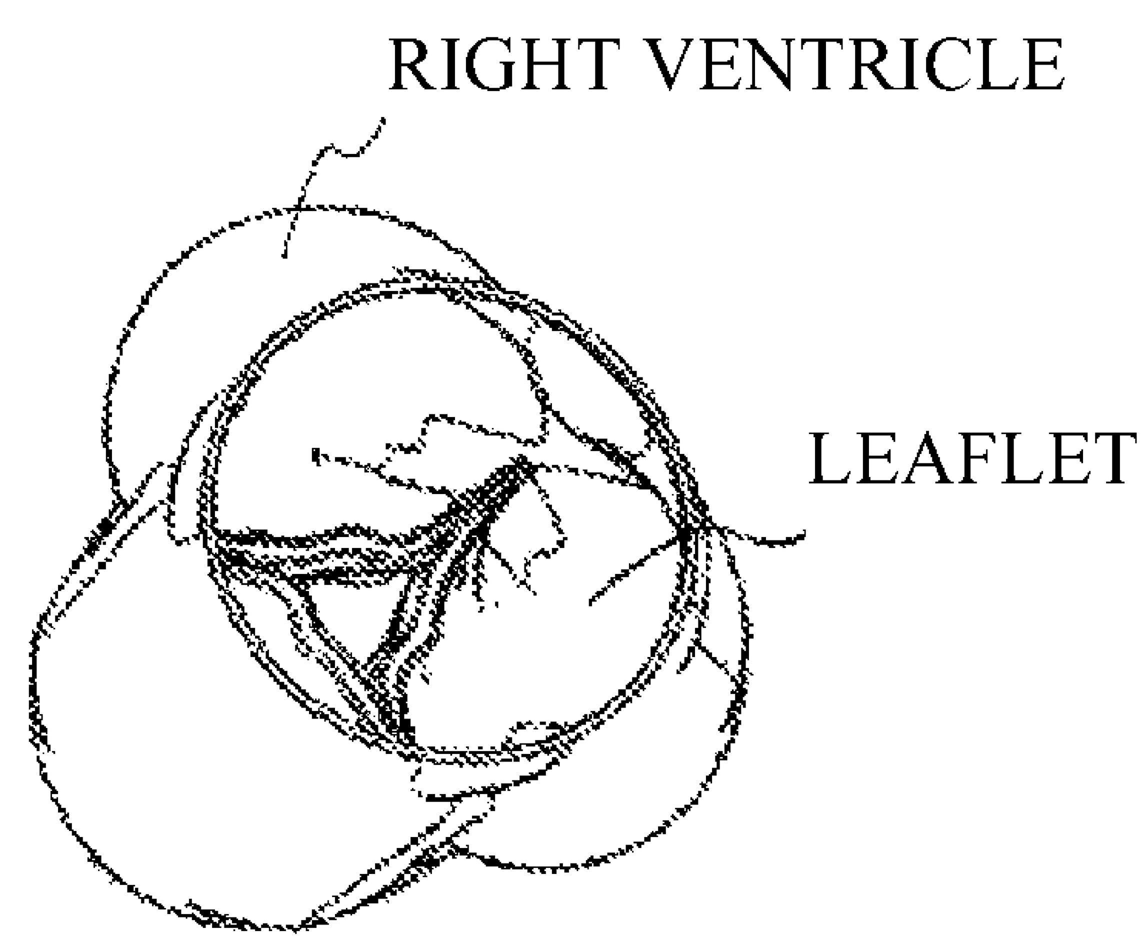


FIG. 18B

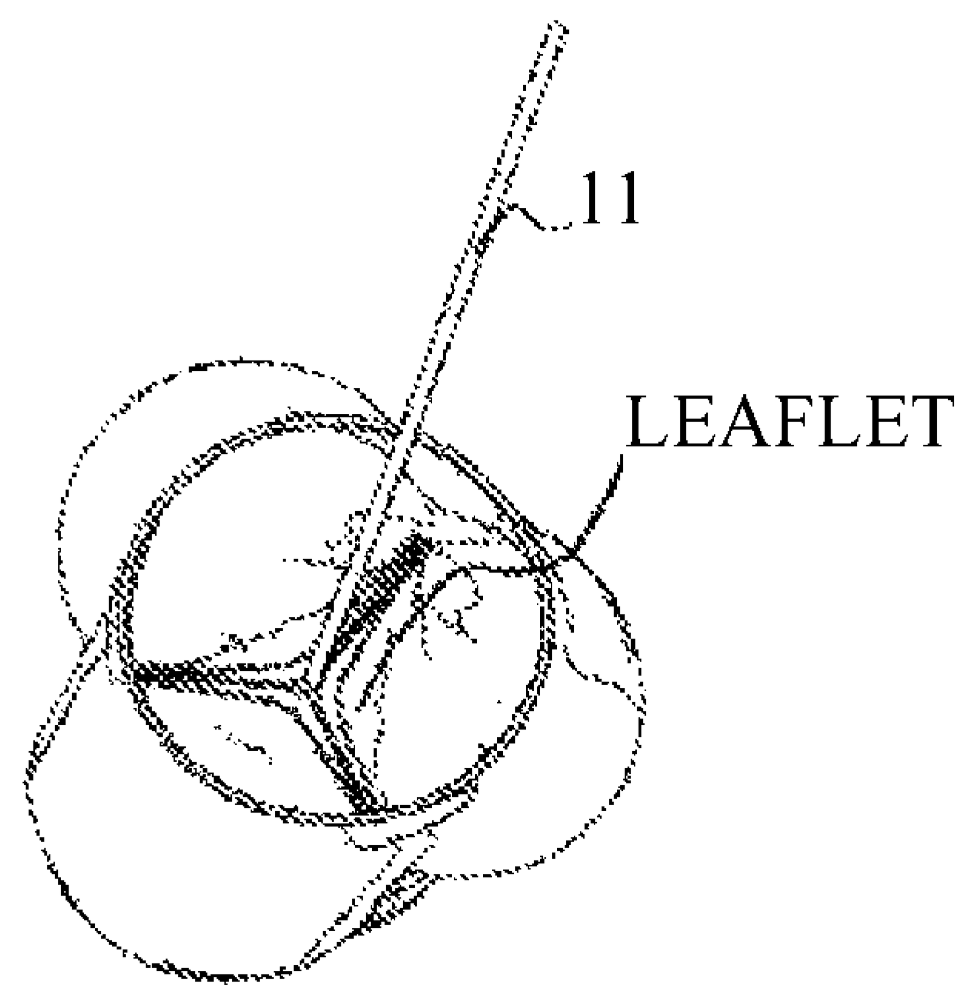


FIG. 19A

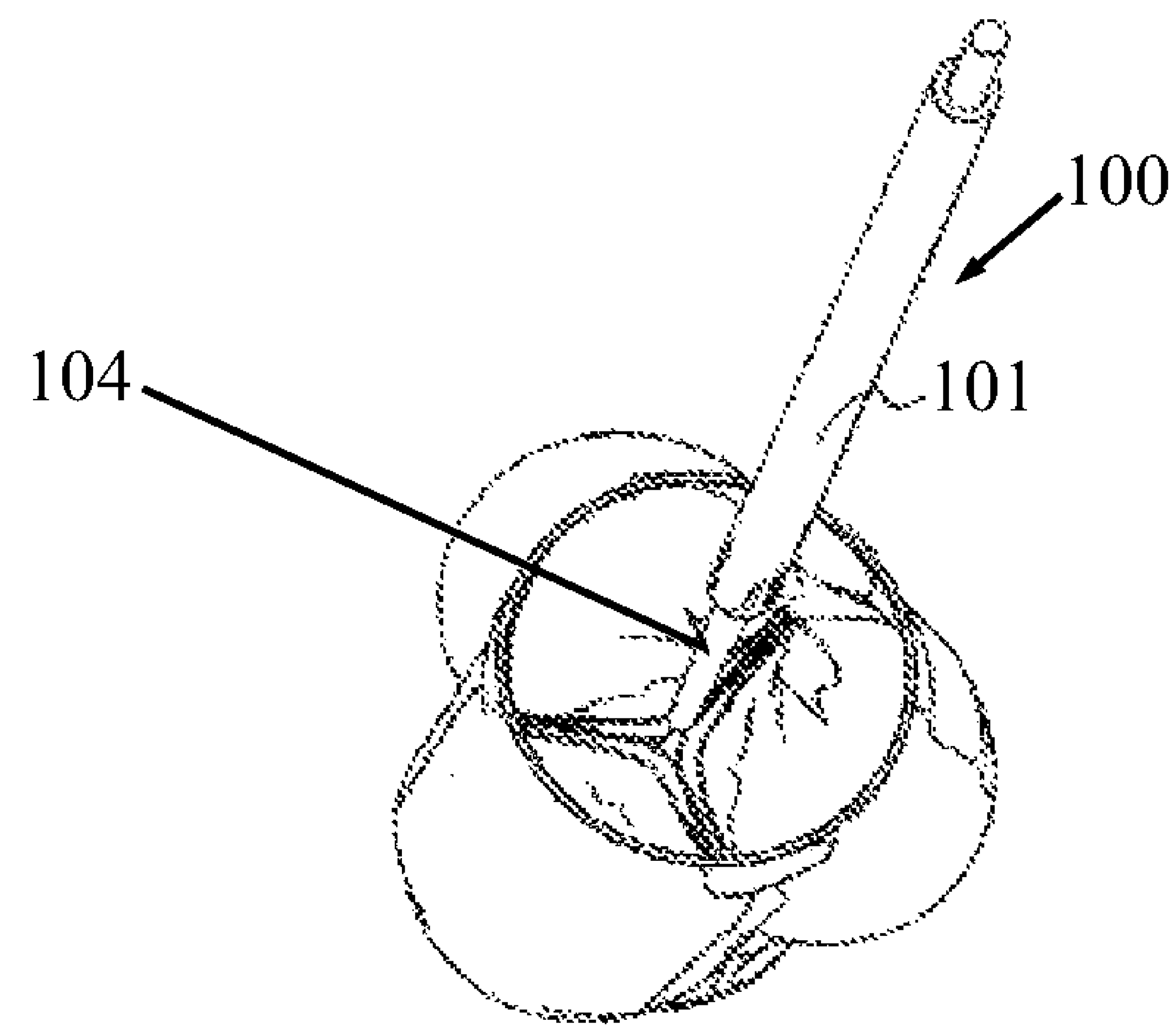


FIG. 19B

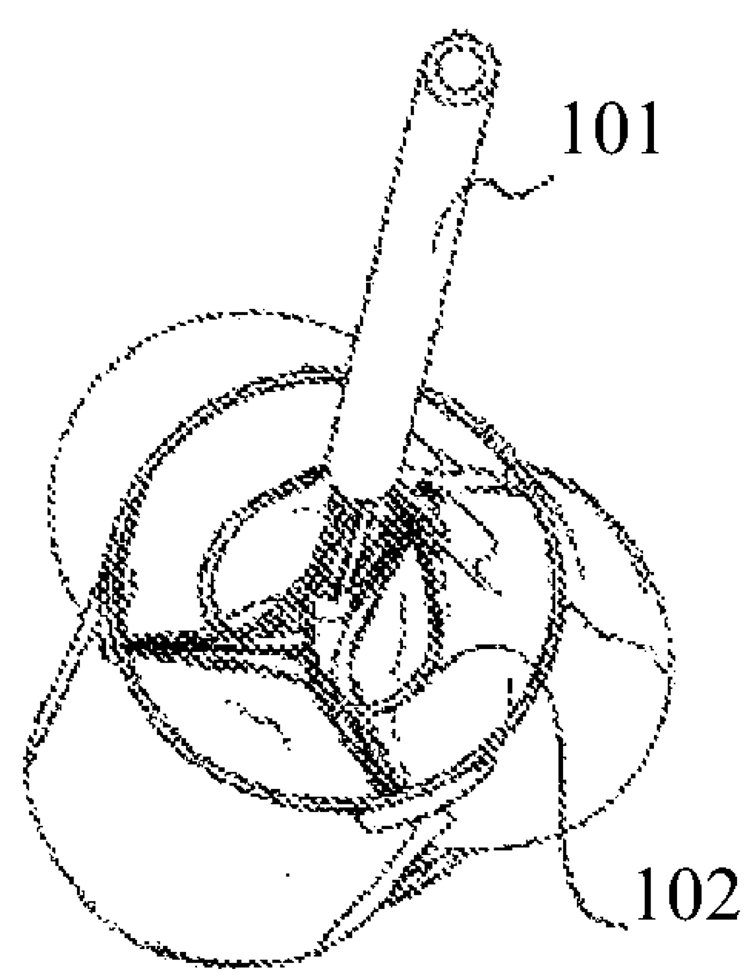


FIG. 19C

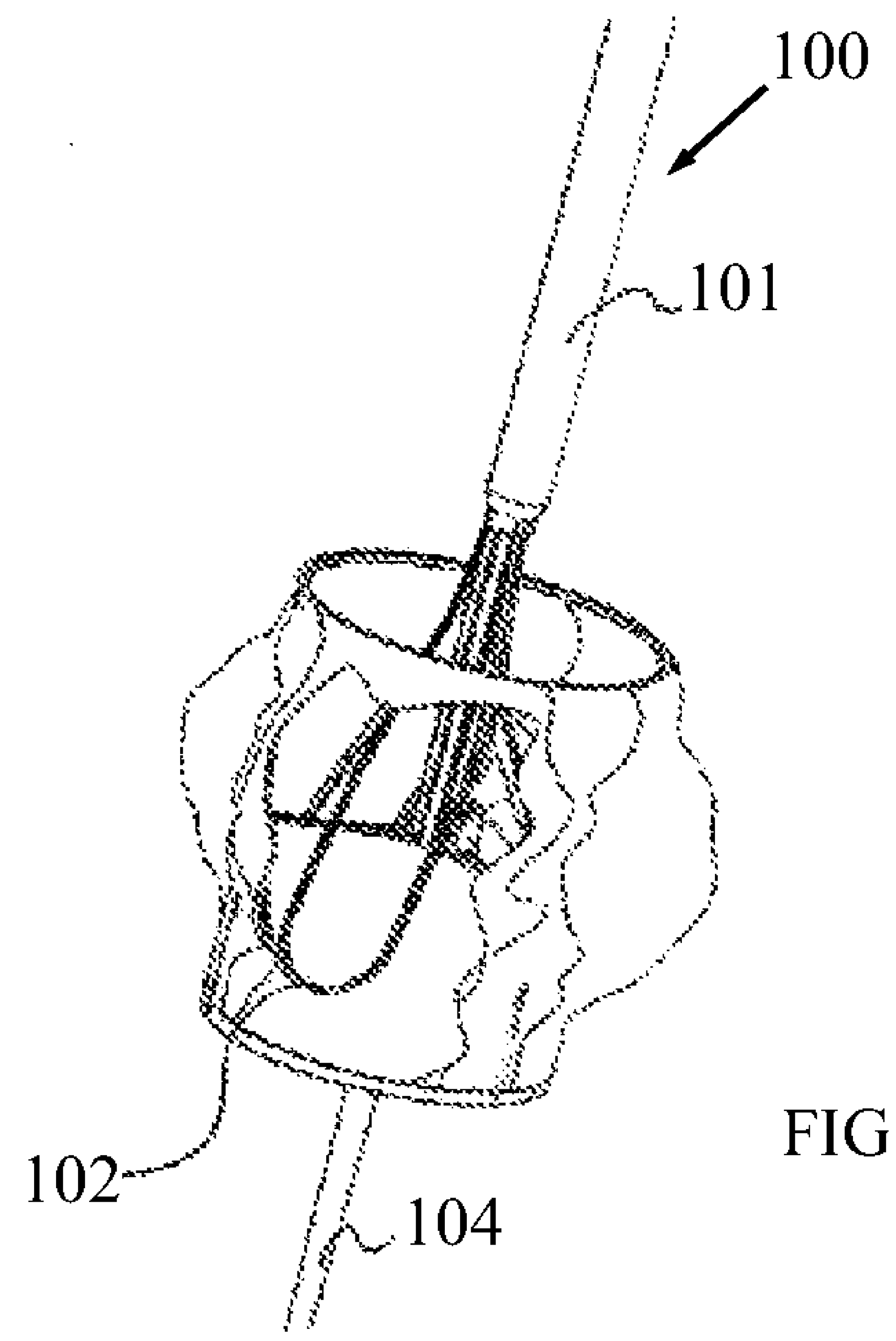


FIG. 19D

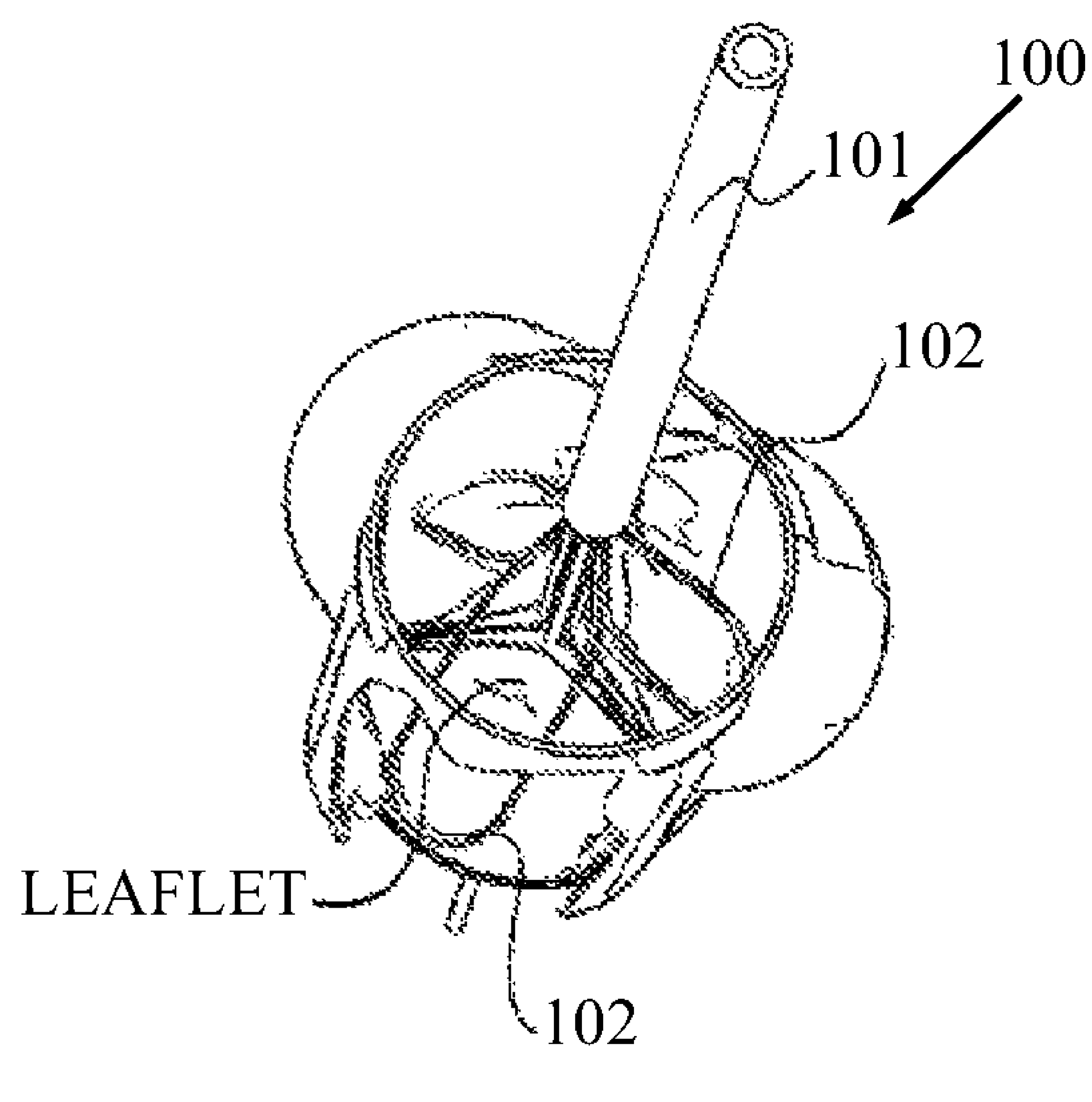


FIG. 19E

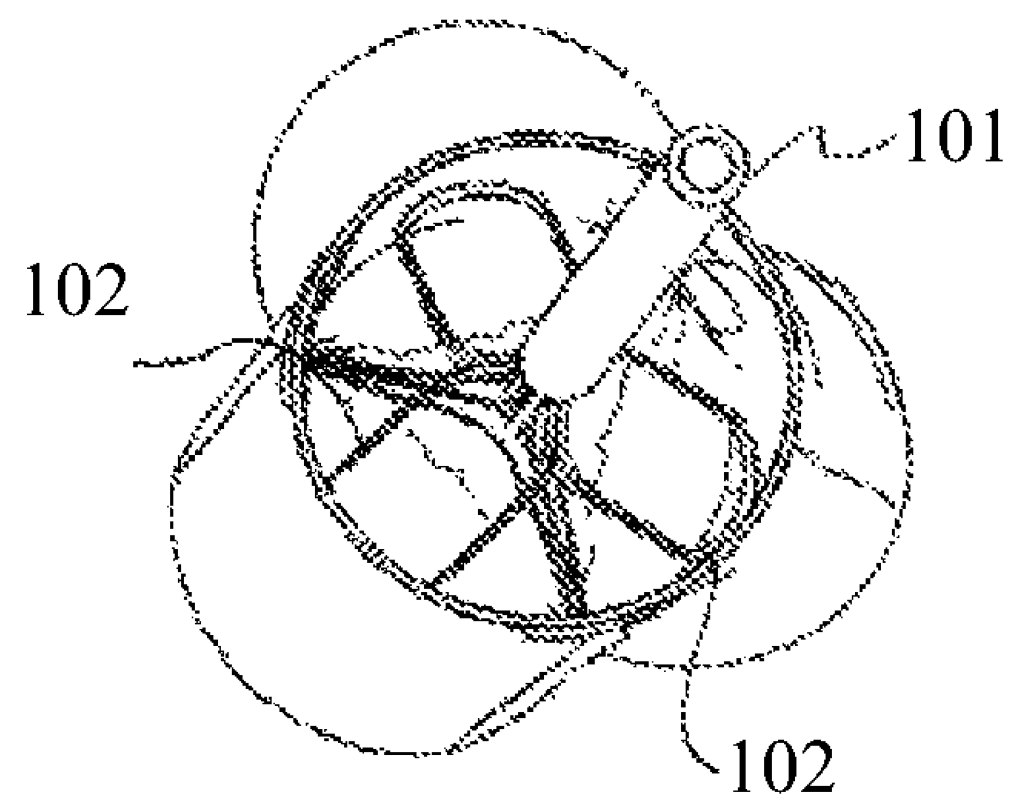


FIG. 19F

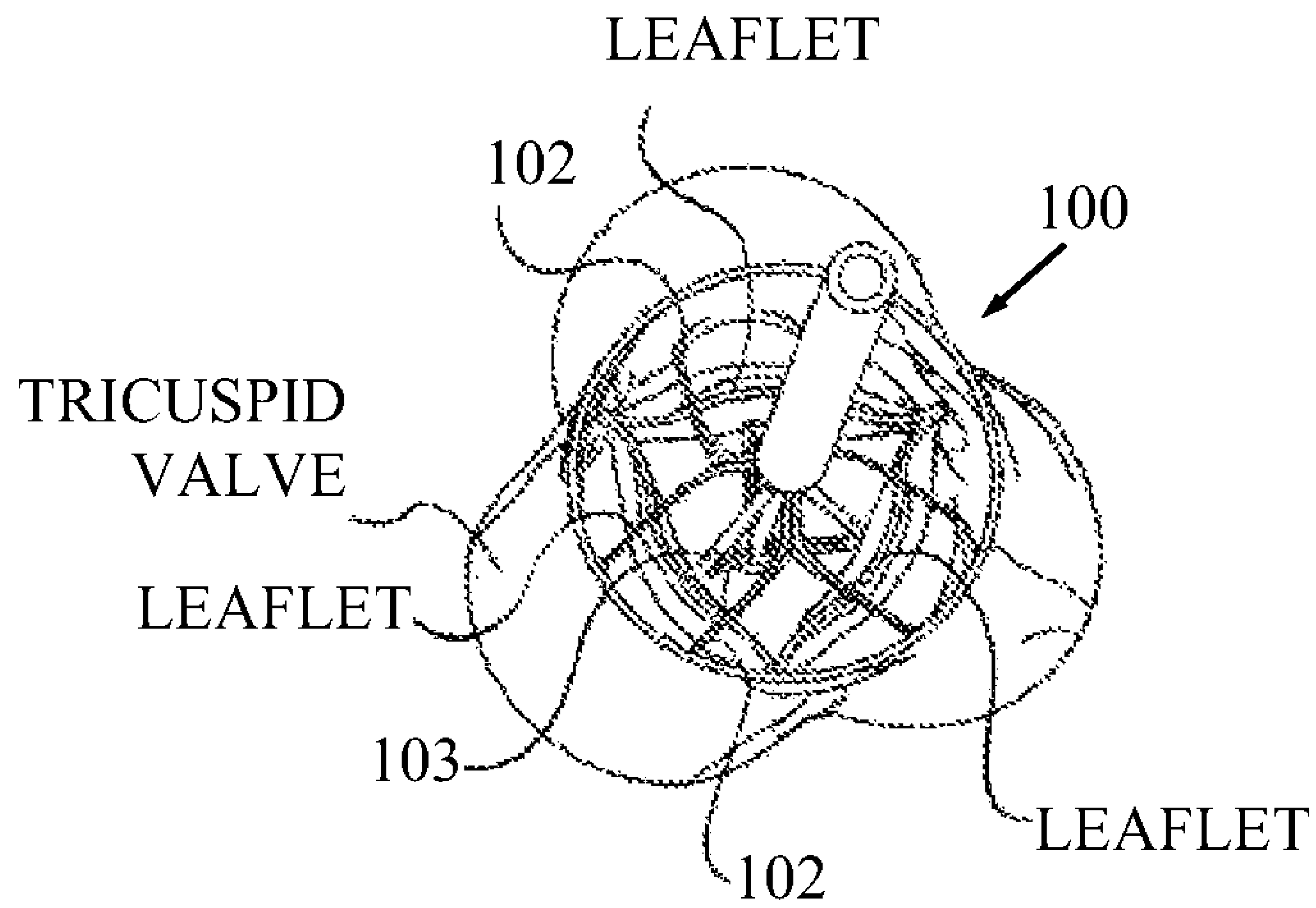


FIG. 19G

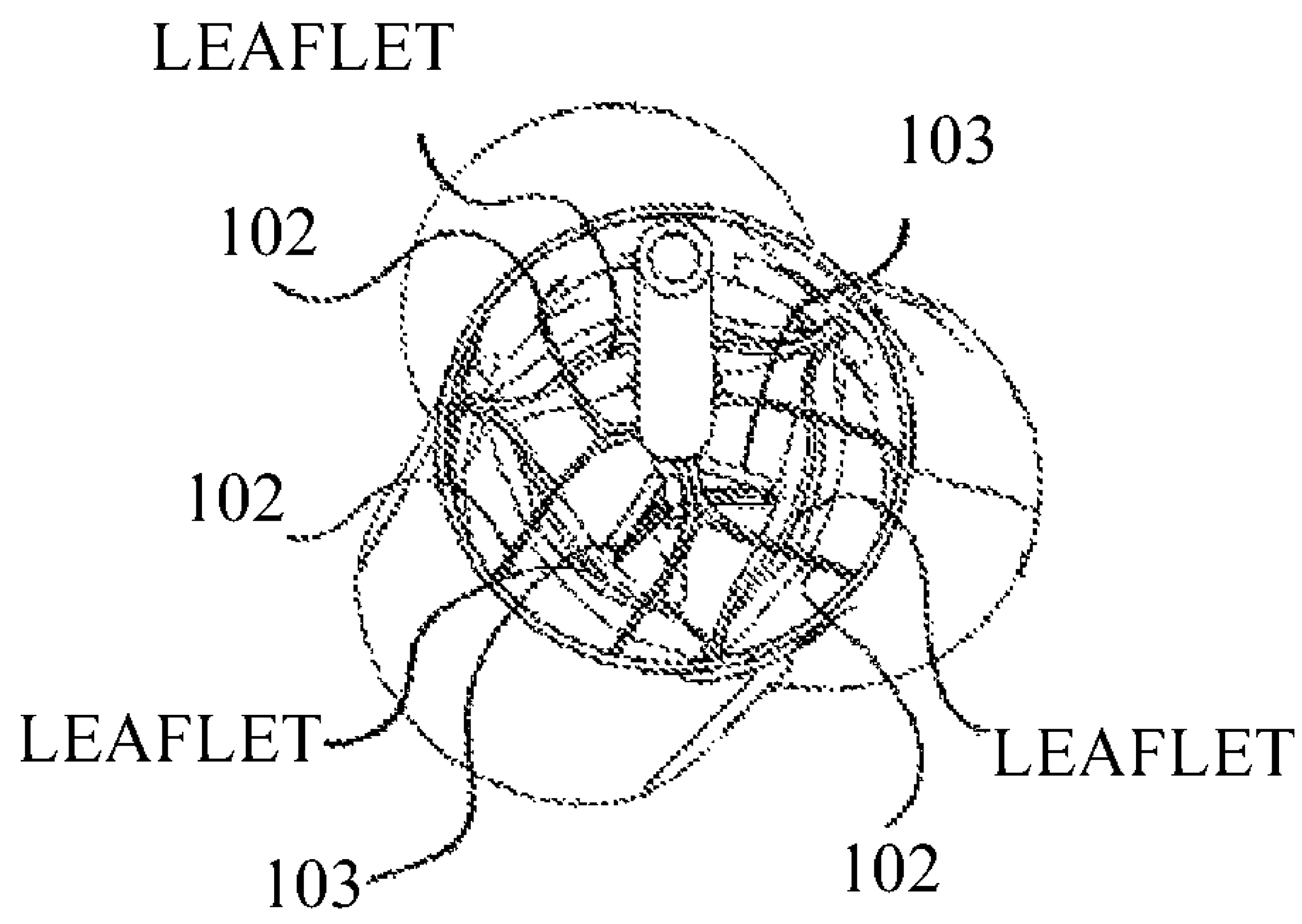


FIG. 19H

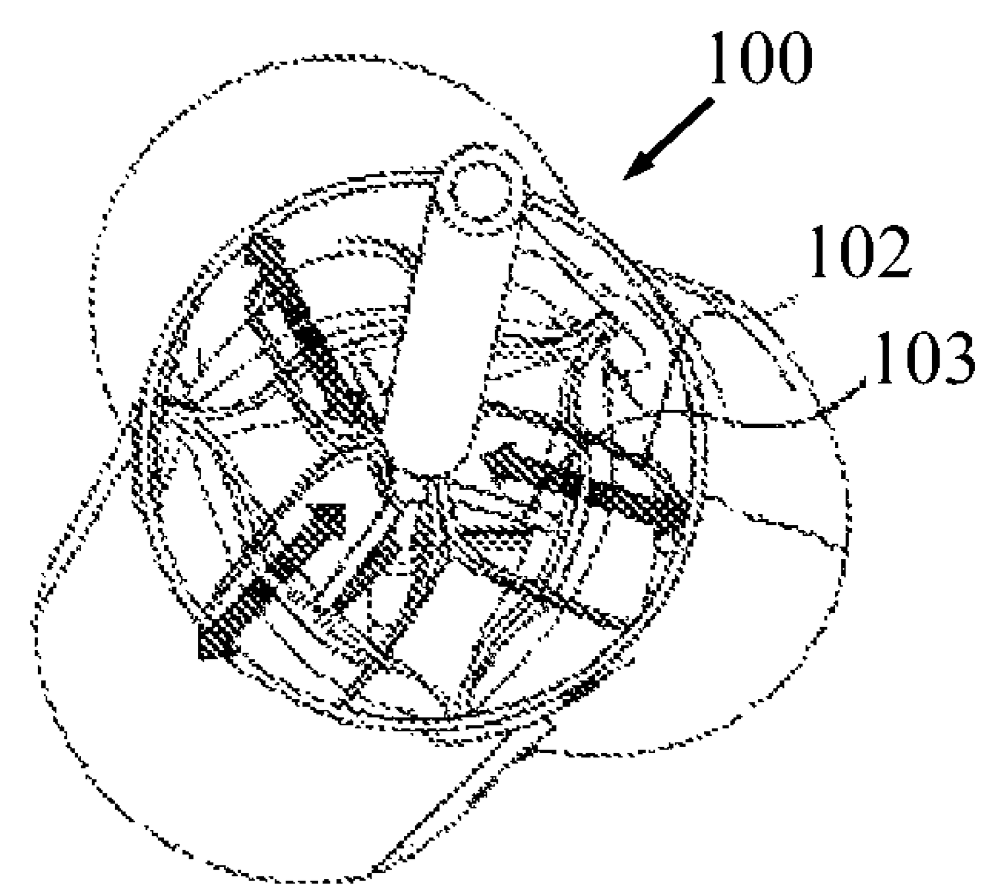
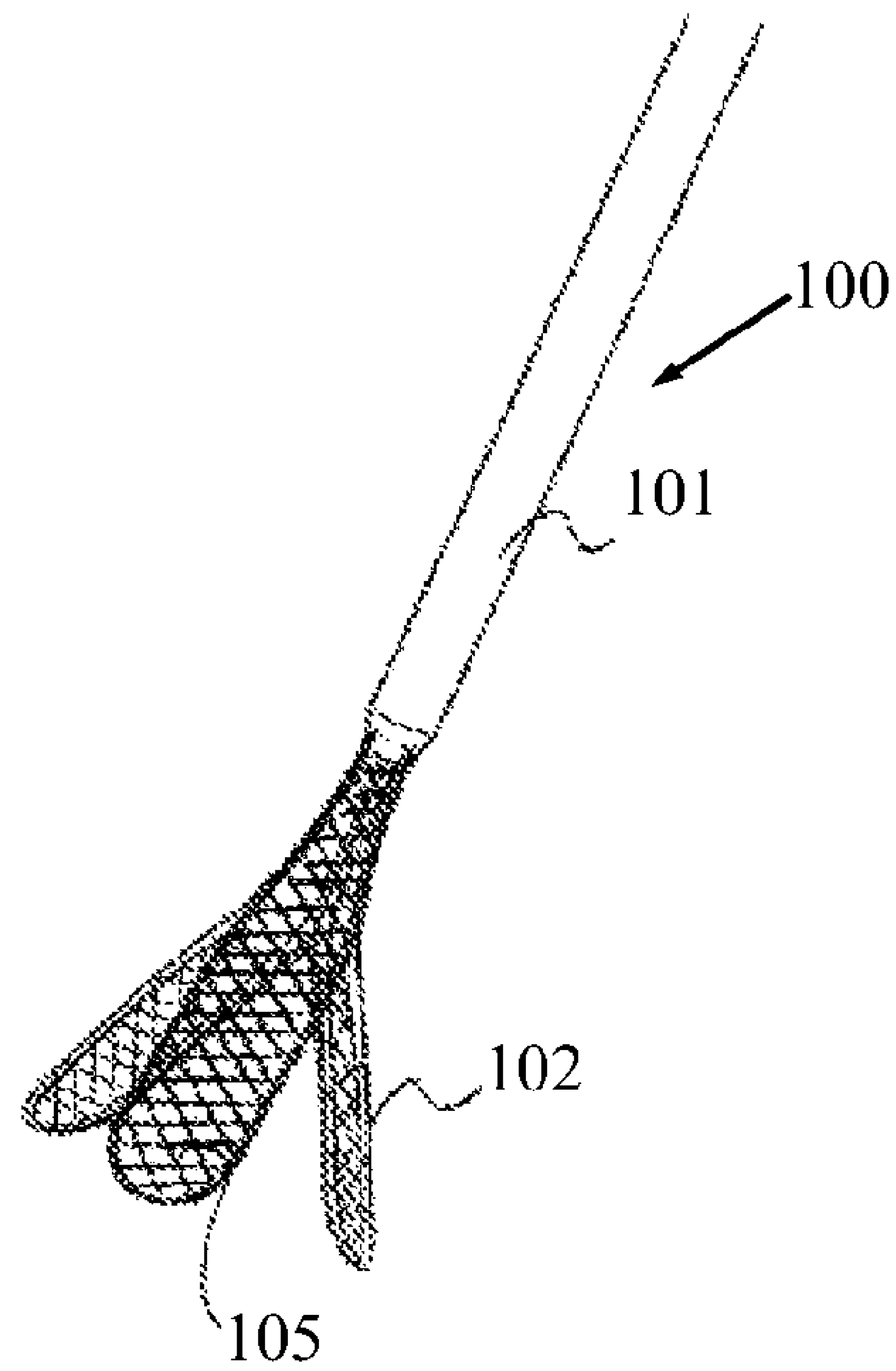


FIG. 19I



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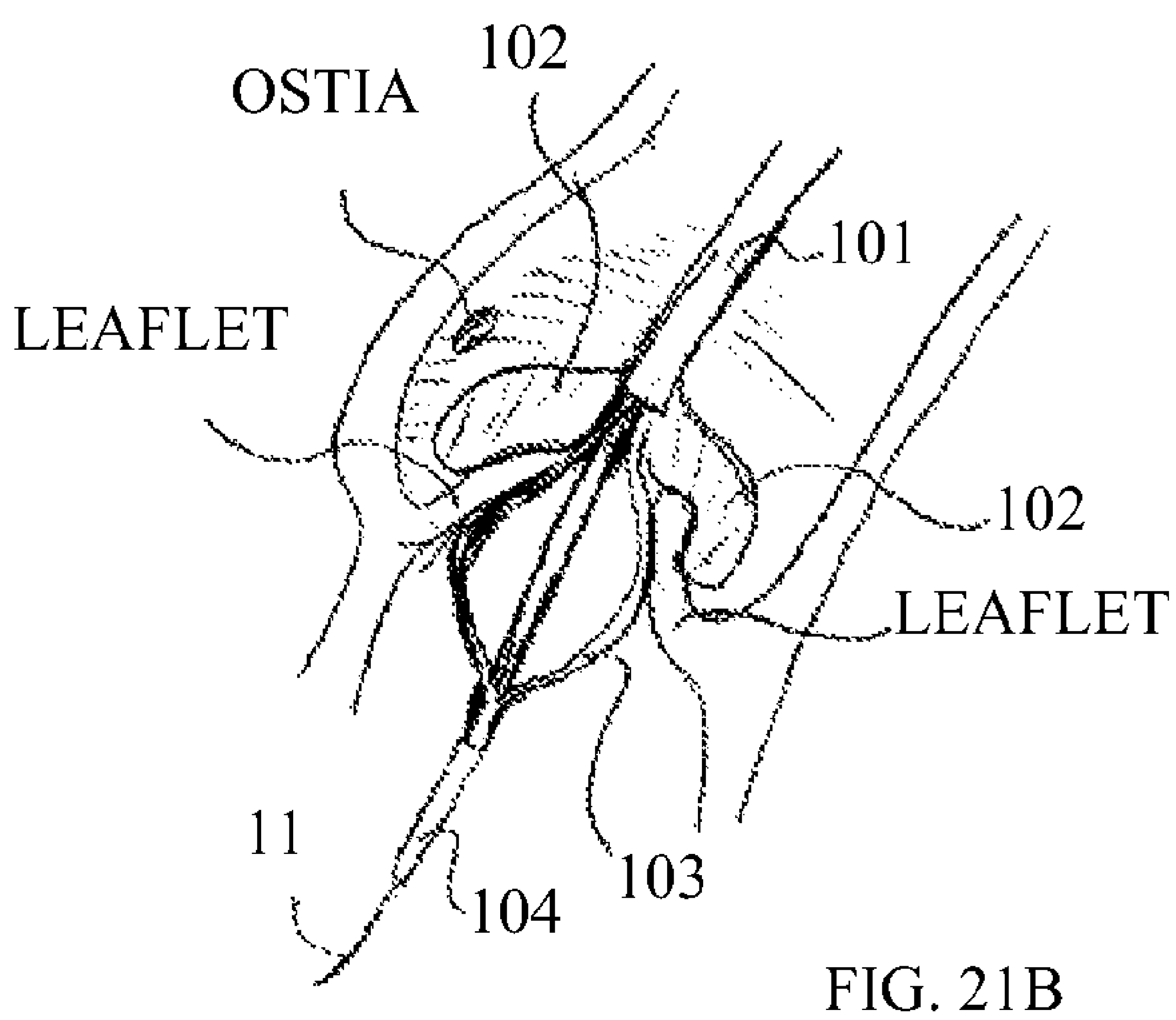

FIG. 21B

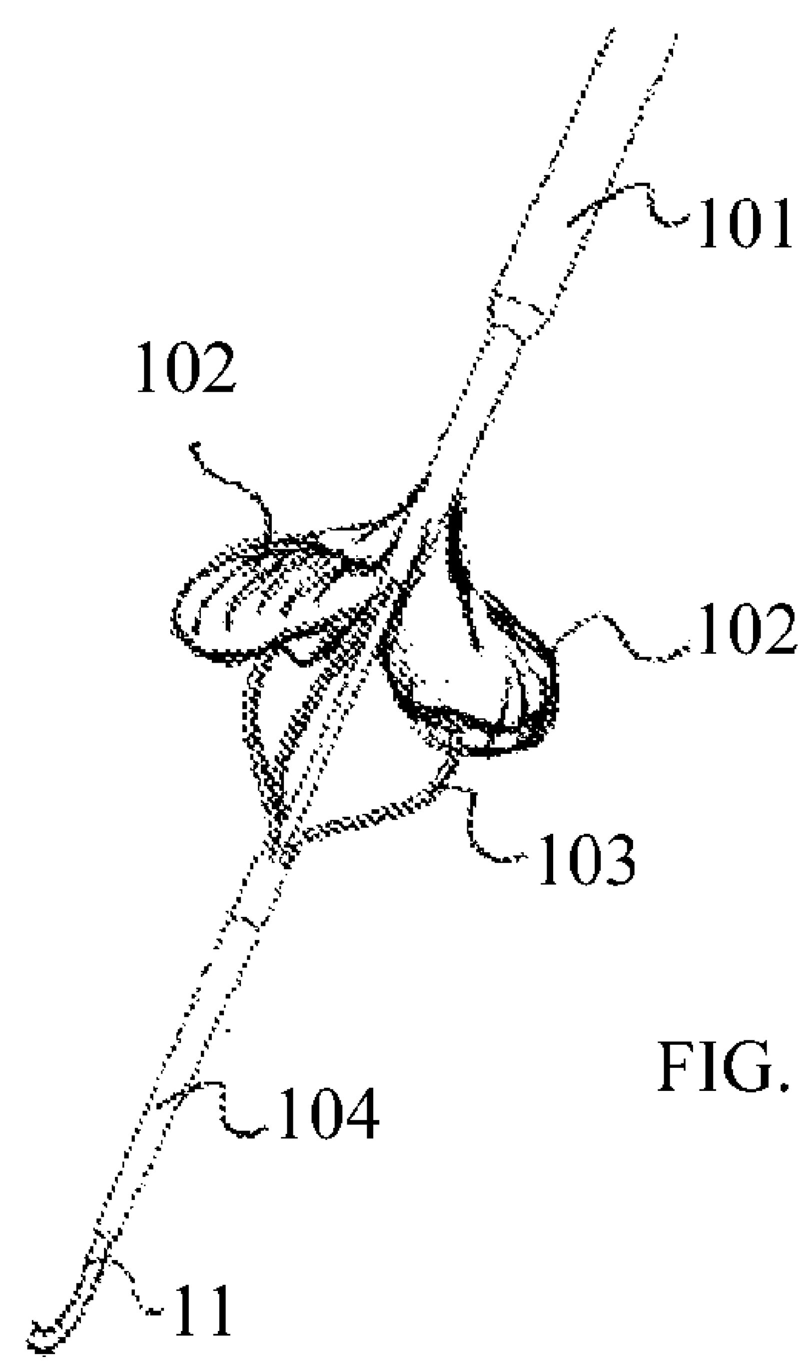

FIG. 21A

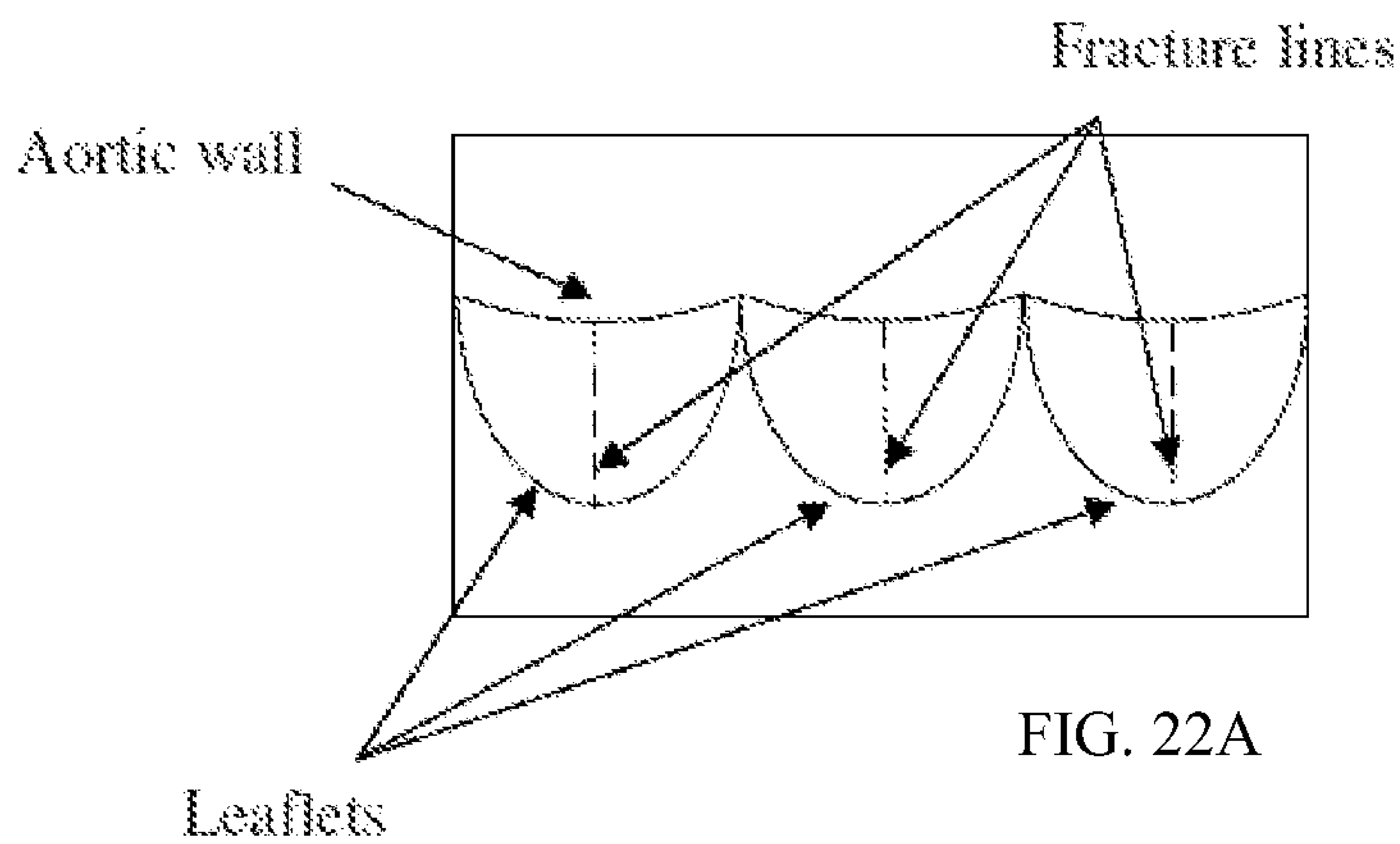

FIG. 22A

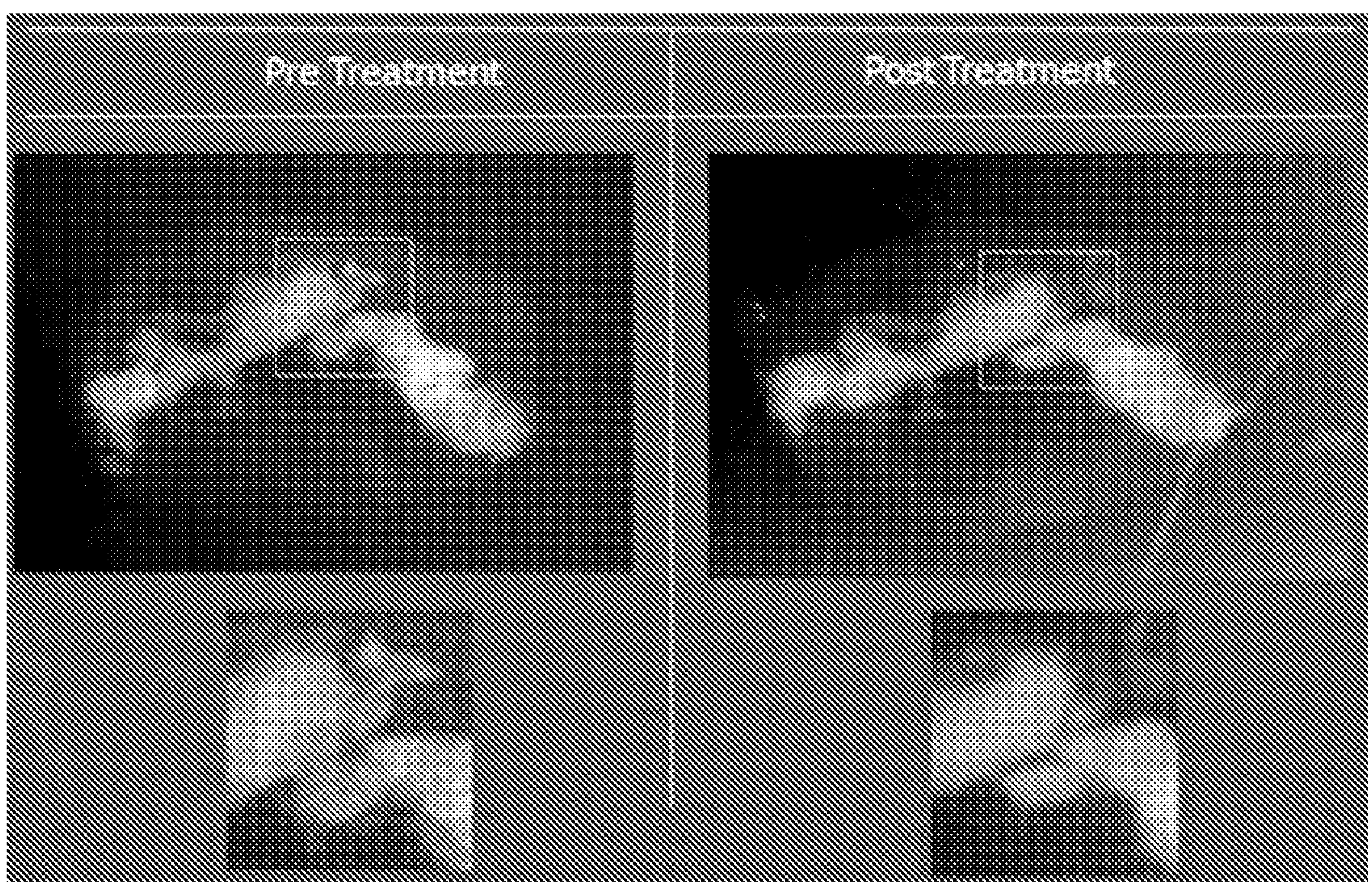

FIG. 22B

FRACTURING CALCIFICATIONS IN HEART VALVES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 USC §119 to U.S. Provisional Patent Application, Ser. No. 61/267029, filed Dec. 5, 2009, and U.S. Provisional Patent Application, Ser. No. 61/356617, filed Jun. 20, 2010, and is a national phase application of PCT/US2010/055810, filed Dec. 3, 2010.

FIELD OF THE INVENTION

The present invention generally relates to devices and methods for fracturing calcifications in heart valves, such as aortic valve leaflets.

BACKGROUND OF THE INVENTION

Essential to normal heart function are four heart valves, which allow blood to pass through the four chambers of the heart in the proper flow directions. The valves have either two or three cusps, flaps, or leaflets, which comprise fibrous tissue that attaches to the walls of the heart. The cusps open when the blood flow is flowing correctly and then close to form a tight seal to prevent backflow.

The four chambers are known as the right and left atria (upper chambers) and right and left ventricles (lower chambers). The four valves that control blood flow are known as the tricuspid, mitral, pulmonary, and aortic valves. In a normally functioning heart, the tricuspid valve allows one-way flow of deoxygenated blood from the right upper chamber (right atrium) to the right lower chamber (right ventricle). When the right ventricle contracts, the pulmonary valve allows blood to flow from the right ventricle to the pulmonary artery, which carries the deoxygenated blood to the lungs. The mitral valve, allows oxygenated blood, which has returned to the left upper chamber (left atrium), to flow to the left lower chamber (left ventricle). When the left ventricle contracts, the oxygenated blood is pumped through the aortic valve to the aorta.

Certain heart abnormalities result from heart valve defects, such as is stenosis or calcification. This involves calcium buildup in the valve which impedes proper valve leaflet movement.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved devices and methods that may be used for fracturing calcifications in aortic valve leaflets, in order to increase leaflet pliability and mobility, either as stand alone treatment, bridge treatment or preparation of the "landing zone" for trans-catheter valve implantation.

The term "fracture" refers to any kind of reduction in size or any modification in shape or form, such as but not limited to, fracturing, pulverizing, breaking, grinding, chopping and the like.

There is provided in accordance with an embodiment of the invention a device for fracturing calcifications in heart valves including a catheter including an external shaft in which are disposed an expandable stabilizer, an impactor shaft on which are mounted expandable impactor arms, and an internal shaft, characterised in that the internal shaft is movable to cause the impactor arms to expand outwards and be locked in an expanded shape, and wherein an impacting element is movable to cause the impactor arms, while in the expanded shape, to move towards the tissue with sufficient energy so as to fracture a calcification located in tissue which is fixed by the stabilizer in a certain position vis-à-vis the impactor arms.

In accordance with a non-limiting embodiment of the invention the impacting element includes the internal shaft which is connected to a distal portion of the impactor arms and which is operative to move relative to the impactor shaft to expand the impactor arms outwards and to cause the impactor arms, while in the expanded shape, to move towards the stabilizer with the sufficient energy. The internal shaft may be lockable relative to the impactor shaft so that the impactor arms are fixed.

In accordance with a non-limiting embodiment of the invention the impacting element includes a weight and a biasing device, wherein the biasing device urges the weight towards the impactor arms with the sufficient energy. In one example, the weight is mounted on the biasing device which is fixed to a distal tip of the catheter. In another example, the weight is fixed to the internal shaft of the catheter. In yet another example, the biasing device includes a pneumatic energy source connected to a pressurized air source.

In accordance with a non-limiting embodiment of the invention the stabilizer includes a stabilizer structure that includes one or more elements (of any form or shape, such as rods, loops or more complex structures) optionally covered by a stabilizer cover. The stabilizer may include a stabilizer structure covered by a covering balloon. An inflate/deflate tube may be inserted into the covering balloon. A first pressure sensor may be located near the stabilizer (in the portion of the catheter that lies in the aorta) and a second pressure sensor may be located near the impactor arms (in the portion of the catheter that lies in the LVOT or left ventricle). The device can be designed in a "reverse" manner for trans-apical use, so that the impactor is proximal and the stabilizer may be positioned at a distal tip of the device. Stabilizer arms may be expandable outwards from the external shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

FIG. **1** is a simplified illustration of the anatomy of a calcified aortic valve, ascending aorta and aortic arch.

FIG. **2** is an enlarged view of a calcified aortic valve.

FIG. **3** is a simplified illustration of a distal part of an impactor catheter system that can be used for fracturing aortic valve calcifications, constructed and operative in accordance with a non-limiting embodiment of the invention.

FIG. **4** is a simplified illustration of several shafts that come out at the proximal side of the catheter of FIG. **3**.

FIG. **5** is a simplified illustration of a device for fracturing calcifications in heart valves, in accordance with another non-limiting embodiment of the present invention, employing a weight.

FIGS. **5**A and **5**B are simplified illustrations of the weight before and after impact, respectively.

FIGS. **6** and **6**A are simplified illustrations of a device for fracturing calcifications in heart valves with a weight, in accordance with yet another non-limiting embodiment of the present invention.

FIGS. **7**-**10**C are simplified illustrations of several types of stabilizers, in accordance with different non-limiting embodiments of the present invention, which can be used to effectively position the distal portion of the device, hold a portion of the leaflets in place during impact and to counteract the impact applied to the ventricular aspect of the valve leaflets.

FIG. **11** is a simplified illustration of impactor arms having more than one arm facing each leaflet, in accordance with a non-limiting embodiment of the present invention.

FIG. **12** is a simplified illustration of an impactor catheter, in accordance with a non-limiting embodiment of the present invention, which optimally maintains valve function during the procedure while allowing continuous measurement of the blood pressure gradient between the left ventricle and the aorta.

FIG. **13** is a simplified illustration of a trans-apical configuration of a device that delivers impact to the calcified valve leaflets, in accordance with a non-limiting embodiment of the invention.

FIG. **14** and FIG. **15** are simplified illustrations of an impactor catheter based on a pneumatic energy source on the proximal side of the catheter and a weight-pull impact mechanism on the distal portion, in accordance with a non-limiting embodiment of the invention.

FIGS. **16**A-**16**D are simplified illustrations of an impactor device, constructed and operative in accordance with another non-limiting embodiment of the present invention.

FIG. **17** is a simplified illustration of the distal end of the device of FIGS. **16**A-**16**D, showing locating and vibratory elements in their open positions.

FIGS. **18**A and **18**B are simplified illustrations of a diseased tricuspid heart valve with diseased leaflets having calcified lesions.

FIGS. **19**A-**19**I are simplified illustrations of a method of using the device of FIGS. **16**A-**16**D, in accordance with another non-limiting embodiment of the present invention.

FIG. **20** is a simplified illustration of the locating elements of the device having a mesh connected to them so as to capture any debris that may be created as part of the process.

FIGS. **21**A and **21**B are simplified illustrations of another embodiment wherein the locating elements are inflatable cushions or balloons.

FIG. **22**A illustrates a longitudinal cut through the aortic wall with fracture lines created at the centerline of the leaflet by an impactor.

FIG. **22**B is an x-ray of a typical leaflet after a single fracture was created close to its centerline.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to FIG. **1**, which illustrates the anatomy of a calcified aortic valve, ascending aorta and aortic arch. Calcifications may be embedded in the valve leaflets, which are connected to the aortic wall just below the coronary ostia.

Reference is now made to FIG. **2**, which is an enlarged view of a calcified aortic valve. The leaflets create concave sinuses on their aortic aspect, just below the coronary ostia. Calcification can be embedded in the leaflets, making the leaflets thicker and less pliable. Specifically, calcification that occurs at the leaflet base, i.e., where the leaflet connects to the annulus or aortic wall, can significantly impair the mobility of the leaflet, similar to friction in a door-hinge.

Reference is now made to FIG. **3**, which illustrates a distal part of an impactor catheter system that can be used for fracturing aortic valve calcifications, constructed and operative in accordance with a non-limiting embodiment of the invention.

A catheter **10** may be delivered over a guide-wire **11** through a vessel, such as the peripheral artery, using a retrograde approach, through the aortic arch and into the ascending aorta, just above the aortic valve. At this stage, all catheter components are still covered by a catheter external shaft **12**. The external shaft **12** is then retracted so that an expandable (e.g., self-expanding) stabilizer **14**, connected to a stabilizer shaft **16**, opens up. Stabilizer **14** is used to guide, position and anchor the catheter distal part in the sinuses, just above the valve leaflets. It is noted that catheter **10** is just one example of a delivery system used to deliver and manipulate a stabilizer and impactor arms described below to impact calcifications. Optionally, the stabilizer and impactor arms described below may be delivered and/or manipulated by other devices other than a catheter, such as a guidewire or system of guidewires and push/pull wires.

An impactor shaft **18**, including impactor arms **20**, is then pushed forward (distally) through the center of the valve into the left ventricle. When pushed forward the impactor arms **20** are folded so that they can easily cross the valve. An internal shaft **22**, which is connected to the distal portion of the impactor arms **20**, is then pulled proximally to cause the impactor arms **20** to open (expand) outwards sideways and lock them in the expanded shape Impactor and internal shafts **18** and **22** are then pulled back (proximally) a bit in order for the impactor arms **20** to make good contact with the ventricular aspect of the leaflets, so that the leaflets are "sandwiched" between the proximally-located stabilizer **14** (from above in the sense of the drawing) and the distally-located impactor arms **20** (from below in the sense of the drawing). In order to fracture leaflet calcifications, impactor arms **20** are pulled abruptly towards the leaflet tissue, while the stabilizer **14** holds the relevant portion of the leaflets in place, by pulling impactor and internal shafts **18** and **22** at a speed of at least 1 m/sec, such as without limitation, around 5-20 m/sec, but with an amplitude of at least 0.5 mm, such as without limitation, about 0.5-3 mm, so that calcification is fractured but soft tissue is unharmed.

Reference is now made to FIG. **4**, which illustrates the several shafts that come out at the proximal side of the catheter **10** shown in FIG. **3**. The entire manipulation of catheter **10** is done by controlling the relative positions of these shafts. For example, as shown in FIG. **3**, the internal shaft **22** is pulled relative to impactor shaft **18** in order to open up impactor arms **20**. The internal shaft **22** and the impactor shaft **18** are locked together so that the impactor arms **20** are fixed. For effective impact to be produced at the distal portion of the catheter, the internal/impactor shafts **22**/**18** are pulled together abruptly relative to the valve leaflet tissue while stabilizer shaft **16** is fixed. The abrupt pull at the proximal side is conveyed to the distal part.

Reference is now made to FIG. **5**, which illustrates an alternative mechanism for generating impact at the distal part of the catheter. A weight **24** is mounted on a biasing device **26** (e.g., a coil spring) that is fixed to a distal tip **28** of the catheter. Before impact (FIG. **5**A), weight **24** is pushed towards distal tip **28** so that biasing device **26** is contracted. In order to generate impact, weight **24** is released so that biasing device **26** is allowed to accelerate the weight **24** until it hits the impactor arms **20** (FIG. **5**B). The impactor arms **20** in turn impact the calcified leaflets. In order to maximize the impact velocity of the impactor arms **20** given a certain momentum of the accelerated weight **24**, the mass of the impactor arms **20** may be diminished. This can be partly achieved by selecting an impactor shaft **18** that is also spring-like, minimizing the pushability of the impactor shaft **18**, or by making the impactor arms **20** "floating" and free to move with no friction with respect to the other parts of the catheter during impact

Reference is now made to FIG. **6**, which illustrates yet another alternative mechanism for generating impact at the distal portion of the catheter. A weight **24**A (can be the catheter tip) is fixed to the internal shaft **22** of the catheter (in this configuration the impactor arms **20** are not connected to the internal shaft **22**). Before impact the internal shaft **22** is pushed distally so that the weight **24**A moves a certain distance (can be a few mm to several centimeters) away from the impactor arms **20**. In order to generate impact, the weight **24**A is now accelerated proximally until it hits the impactor arms **20** with high velocity. A biasing device **26**A (one version of which is illustrated in FIG. **6**A), a pneumatic mechanism, or any other mechanism can be used in order to generate the required acceleration of the mass. The advantage of this method over the method described in FIGS. **3-4** is that when the energy source is external, it may be easier to generate high velocities at the distal portion of the catheter by using more powerful biasing devices or energy sources.

Reference is now made to FIGS. **7-10**, which illustrate several types of stabilizers, which can be used to effectively position the distal portion of the catheter relative to the valve anatomy, hold certain portions of the valve leaflets in place during impact and also counteract the impact applied to the ventricular aspect of the valve leaflets. Ideally one would like to maximize the counteract force on the aortic aspect of the leaflets during impact while making sure the stabilizer surface is sufficiently compliant and blunt so to minimize injury to the leaflet surface.

Reference is now made to FIG. **7**, which illustrates an stabilizer structure **30** that can take the form of one or more loops (e.g., at least one loop fits into each of the sinuses above the leaflets, two or more for bicuspid aortic valves and three or more for tricuspid aortic valves). The stabilizer structure **30** is (optionally) covered by a stabilizer cover **32**, which can be a thin metal mesh (net), a solid plastic surface, etc. If the stabilizer cover **32** is solid, or if it is based on a net with pores that are small enough, then the stabilizer cover **32** can be used as an embolic protection means, i.e., at the end of the impact procedure, if any emboli have been generated, then they can be safely collected into the catheter when folding back the stabilizer using the external shaft.

Reference is now made to FIG. **8**, which illustrates an alternative stabilizer design, which incorporates a covering balloon **34** on each stabilizer structure **30**. Each balloon **34** is elongated and its central axis follows the curvature of the loops that make up the stabilizer structure **30**. The loops can also be used as inflate/deflate tubes for the balloons, with fluid for the inflation passing through one or more inflation/deflation openings **36**. The great advantage of the balloon-based stabilizer is that the stabilizer can be positioned in the sinuses with the balloons deflated. Then the balloons **34** can be inflated to generate full contact with the leaflets surface, maximizing the impact counteract force, while avoiding injury.

Reference is now made to FIG. **9**, which illustrates yet another design of a balloon-based stabilizer. Each of the three covering balloons **34** covers one of the stabilizer structure loops **30**. An inflate/deflate tube **38** can be inserted into each balloon on its proximal side. FIG. **10**A illustrates balloon **34** as viewed from above. FIGS. **10**B and **10**C illustrate balloon **34** from the side, respectively deflated and inflated.

Reference is now made to FIG. **11**, which illustrates another configuration of impactor arms **20**, which comprises more than one arm facing each leaflet. It may be readily understood that the number and geometry of the impactor arms are based on the optimal locations where one wishes to impact the leaflets, e.g., number and orientation of impact lines, points or regions per leaflet, impact closer to leaflet base or tip, etc.

Reference is now made to FIG. **12**, which illustrates a configuration of the impactor catheter, which optimally maintains valve function during the procedure while allowing continuous measurement of the blood pressure gradient between the left ventricle and the aorta. The impactor arms **20** and stabilizer structure **30** contact the leaflets only at their bases, i.e. near the annulus, where heavily calcified leaflets are typically immobile. The leaflet tips remain free to move, so that overall valve function is almost undisturbed by the device when it delivers impact. Two pressure sensors, a first pressure sensor **40** above the valve (near the stabilizer) and a second pressure sensor **42** below the valve (near the impactor arms) measure the aortic and ventricular blood pressures, respectively. This allows continuous measurement of the pressure gradient across the valve, which can be used as a very important real time feedback for the success of the procedure. Alternatively to incorporating pressure sensors in the device, one can design sufficiently large conduits in the catheter having a distal opening at each region of interest where pressure needs to be measured and a proximal port that can be connected to a pressure sensor outside the patient body.

Reference is now made to FIG. **13**, which illustrates a trans-apical configuration of a device that delivers impact to the calcified valve leaflets. Similar elements are similarly designated as above. The trans-apical approach, while being more invasive than the trans-femoral approach, allows the device to be rigid and short, thereby potentially improving the delivery of impact from the proximal (external) portion of the device to the impactor arms on its distal portion. The stabilizer **14** is positioned closer to the distal tip **44** of the device. The tip **44** must first cross the valve and open the stabilizer **14** to position the device, hold certain portions of the leaflets and counteract the impact.

Reference is now made to FIG. **14** and FIG. **15**, which illustrate an embodiment of an impactor catheter based on a pneumatic energy source on the proximal side of the catheter and a weight-pull impact mechanism on the distal portion. Again, similar elements are similarly designated as above.

Reference is now made to FIG. **14**, which illustrates the distal end of the catheter. The catheter is delivered over guide wire **11** into the valve. The external sheath (shaft) **12** is retracted to expose stabilizer arms **50** which expand outwards from external shaft **12**. (Stabilizer arms **50** extend from a stabilizer shaft **51** shown in FIG. **15**.) The catheter is then pushed distally until stabilizer arms **50** make sufficient contact with the aortic aspect of the valve leaflets. The impactor is then advanced through the center of the valve (over guide wire **11**) into the LVOT (Left Ventricular Outflow Tract).

This embodiment includes impactor arms **52**, which are preferably, but not necessarily, cut out of a nitinol tube and are pre-shaped to be normally half-open. The distal ends (or one common distal end) of the impactor arms **52** are/is fixed (e.g., welded) to an internal tube (shaft) **54** which is free to move back and forth inside the impactor tube (shaft) **18**. When the internal tube **54** is pulled proximally by the operator on the proximal side of the catheter, the impactor arms **52** extend outwards sideways, increasing the impactor diameter. When the internal tube **54** is pushed distally, the impactor arms **52** close or decrease their diameter. Varying the relative position of the internal tube **54** relative to impactor shaft **18** allows the operator to set the optimal impactor diameter per treated valve during the procedure. Furthermore, it allows the operator to select the regions on the calcified leaflets, which are impacted. Another option shown in this embodiment is the capability to rotate the impactor vis-à-vis the stabilizer (or together with the stabilizer) and the valve leaflets, in order to impact yet additional (or different) regions on the valve leaflets. Upon setting the impactor arms diameter and angular position, these settings can be now locked by the user (by locking the position of the internal tube **54** at the control side of the catheter in the hands of the operator). The impactor is now pulled gently until it makes sufficient contact with the ventricular side of the leaflets and is now locked in longitudinal position as well.

Weight **24** can be pulled proximally as described above by means of a weight pull shaft **56**.

Reference is now made to FIG. **15**, which illustrates the proximal side of the impactor catheter described in FIG. **14**. A pneumatic energy source **58** (which serves as the biasing device) is connected to a pressurized air source **60** (operating room wall inlet, compressor, balloon etc.). The body of the pneumatic energy source **58** is preferably connected to the stabilizer shaft **51**, in order to counteract the impact applied to the valve leaflets on the distal portion of the catheter. The longitudinal position of the internal shaft **54** with respect to the impactor shaft **18**, as well as the longitudinal and angular position of the impactor shaft **18**, are set and locked by the user as described in FIG. **14**. The weight/pull shaft **56** is now pushed to the most distal position and then connected to a piston **62** and proximal mass **64**. Piston **62** is arranged to slide in a main cylinder **66**, which houses a pneumatic valve **68** and which is open to air flow from an air container **70** via an air inlet **72**. When pneumatic valve **68** is opened by the operator, the pressurized air in air container **70** is released through air inlet **72** into main cylinder **66**, thereby accelerating piston **62** and proximal mass **64** rapidly over a certain distance. Piston **62** and proximal mass **64** gain relatively high energy (momentum) while pulling the weight/pull shaft **56** that are connected to the distal weight **24** at the tip of the catheter. Upon reaching a certain travel distance, the distal weight **24** hits the impactor arms **52**, which then transfers the energy to the valve calcification to produce fractures. Using the weight/pull mechanism allows to transfer high impact energy over a flexible catheter.

Reference is now made to FIGS. **16**A-**16**D, which illustrate an impactor device **100**, in accordance with another non-limiting embodiment of the present invention. Device **100** includes an outer sheath **101** in which are disposed one or more locating elements **102** and one or more (radially) vibratory (impacting) elements **103**. Device **100** has a tip **104** which allows it to be guided through the vasculature over guidewire **11**. FIGS. **16**A through **16**D show the gradual withdrawal of outer sheath **101** and the opening of the locating elements **102**. FIG. **16**D shows the radial opening of vibratory elements **103**.

The vibratory mechanism is an active device which can be made to move in-and-out in the radial direction with a frequency and amplitude that is determined by the operator, or comes preset by the manufacturer. The inner vibratory mechanism proceeds to vibrate against the inside of the native leaflet, applying force at a specified location, while the locating elements having been positioned earlier, and provide resistance to said force. The resulting action can remodel the calcification structure within the leaflet.

The vibratory mechanism can be constructed as a tube having slits cut axially around its circumference. Should the tube be compressed such that its ends move one towards the other, the material between the circumferentially cut slits would extend radially outward (elements **103**).

Reference is now made to FIG. **17**, which illustrates the distal end of device **100** with both locating and vibratory elements **102** and **103** in their open positions, respectively. It is noted that vibratory elements **103** may be distributed equally or unequally around the circumference of the device **100**.

FIGS. **18**A and **18**B illustrate a diseased tricuspid heart valve with diseased leaflets having calcified lesions. The opening of the valve (FIG. **18**B) is adversely affected by the calcification.

Reference is now made to FIGS. **19**A-**19**I, which illustrate the treatment of the diseased valve using the device. Guidewire **11** is introduced into the artery and advanced until its distal end passes through the valve leaflets. In the case of the aortic valve, the guidewire **11** would be advanced until its distal end is located within the left ventricle. The device **100** is advanced over the guidewire **11** until its distal end is located at or near the valve annulus. Outer sheath **101** is withdrawn partially, exposing the locating mechanism whose elements **102** extend radially outward. The device **100** is moved in a distal direction (towards the left ventricle in the case of the aortic valve) so that locating elements **102** rest against the pocket between the downstream surface of the leaflets and the arterial wall. The device **100** can be rotated gently in order to facilitate the proper positioning of the elements **102**.

Once in place, the vibrating mechanism is actively expanded radially so that vibratory elements **103** rest against the inside or upstream surface of the valve leaflets. Pre-tensioning the vibrating elements **103** against the leaflets is possible, such that tension is maintained against the leaflet tissue which is sandwiched between the locating elements **102** and the vibrating elements **103**.

The operator can now begin the vibratory motion of elements **103** so that a repetitive force is applied to the inner surface of the leaflets, thus affecting a change in the structure of the calcific buildup within the leaflet tissue.

Reference is now made to FIG. **20**, which illustrates the locating elements **102** having a mesh **105** connected to them so as to capture any debris that may be created as part of the process. The mesh can be distributed around the locating elements **102**, and can be made out of a wide range of suitable materials.

Reference is now made to FIGS. **21**A and **21**B, which illustrate another possible embodiment wherein the locating elements **102** are inflatable cushions or balloons. The balloons are often filled with a liquid such as saline, and can offer the counter force needed in order to resist the force generated by the vibratory mechanism. The balloons are inflated in such a way as not to block the coronary ostia.

FIG. **22**A illustrates a longitudinal cut through the aortic wall with fracture lines created at the centerline of each leaflet by an impactor (which, for example, has three impacting arms). Similarly any number and pattern of fractures can be pre-set or achieved. FIG. **22**B is an x-ray of a typical leaflet after a single fracture was created close to its centerline.

The scope of the present invention includes both combinations and subcombinations of the features described hereinabove as well as modifications and variations thereof which would occur to a person of skill in the art upon reading the foregoing description and which are not in the prior art.

What is claimed is:

1. A device for fracturing calcifications in heart valves comprising:

an expandable stabilizer and expandable impactor arms assembled on and deployed by a delivery system, wherein said delivery system is operable to move said impactor arms, while in an expanded position, with respect to said stabilizer with sufficient energy so as to fracture a calcification located in tissue which is sandwiched between said stabilizer and said impactor arms, wherein said delivery system comprises a catheter, in which are disposed said expandable stabilizer, an internal shaft and an impactor shaft on which are mounted said impactor arms, and wherein said internal shaft is movable to cause said impactor arms to expand outwards and be locked in an expanded shape, distal portions of said impactor arms being distanced from said impactor shaft, and wherein an impacting element is movable to cause said impactor arms, while in the expanded shape, to move linearly with respect to said stabilizer with sufficient energy so as to fracture a calcification located in tissue which is sandwiched between said stabilizer and said impactor arms.

2. The device according to claim **1**, wherein said impacting element comprises said internal shaft which is connected to a distal portion of said impactor arms and which is operative to move relative to said impactor shaft to expand said impactor arms outwards and to cause said impactor arms, while in the expanded shape, to move towards said stabilizer with the sufficient energy.

3. The device according to claim **1**, wherein said internal shaft is lockable relative to said impactor shaft so that said impactor arms are fixed.

4. The device according to claim **1**, wherein the sufficient energy is associated with moving said impactor arms towards said stabilizer at a speed of at least 1 m/sec and an amplitude of at least 0.5 mm.

5. The device according to claim **1**, wherein said impacting element comprises a weight and a biasing device, wherein said biasing device urges said weight towards said impactor arms with the sufficient energy.

6. The device according to claim **5**, wherein said weight is mounted on said biasing device which is fixed to a distal tip of said catheter.

7. The device according to claim **5**, wherein said weight is fixed to said internal shaft of said catheter.

8. The device according to claim **5**, wherein said biasing device comprises a pneumatic energy source connected to a pressurized air source.

9. The device according to claim **1**, wherein said stabilizer comprises a stabilizer structure covered by a stabilizer cover.

10. The device according to claim **1**, wherein said stabilizer comprises a stabilizer structure covered by a covering balloon.

11. The device according to claim **10**, wherein an inflate/deflate tube is inserted into said covering balloon.

12. The device according to claim **1**, further comprising a first pressure sensor located near said stabilizer and a second pressure sensor located near said impactor arms.

13. The device according to claim **1**, wherein said stabilizer is positioned distal to said impactor arms.

14. The device according to claim **1**, wherein said stabilizer comprises stabilizer arms which are expandable outwards.

15. A method for fracturing calcifications in heart valves comprising using the device of claim **1** and moving said internal shaft to cause said impactor arms to expand outwards, and moving said impacting element to cause said impactor arms, while in the expanded shape, to move linearly with respect to said stabilizer with sufficient energy so as to fracture a calcification located in tissue which is sandwiched between said stabilizer and said impactor arms.

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